Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 4/23/2018 7:27:19 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: ACC Comments
Attachments: ACC Comments on New Chemicals Review Program Implementation 1-19-2018.pdf; ACC Comments - Not Likely to Present Table.xlsx; ACC Comments - SNUR Table.xlsx; ACC Comments on New Chemicals Review Program Under TSCA as Amended final 20170117.pdf

Erik, here are the comments we've filed with the Agency on Section 5. Please let me know if you have any questions. Mike

PMN #	Chemical Name	CAS Number	PMN Submitter Name	Date PMN Filed	EPA Review Start Date	Date of "Not Likely to Present an Unreasonable Risk" Determination	Number of Days to Not Likely Determination From Date PMN Filed	Number of Days to Not Likely Determination From Review Start Date	Basis for Action	PMN Notice Federal Register Citation and Link	Not Likely Determination Federal Register Citation and Link
P-17-0293	Substituted carbomonocycle, polymer with substituted carbonomoncycles, alkyl substituted- alkanediols, alkanediol, alkanedioic acid, and dialkylene glycol	Not available	Allnex USA, Inc.	April 24, 2017	April 24, 2017	July 21, 2017	88	88	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	82 FR 31598 (July 7, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-07/pdf/2017-14326.pdf	82 FR 47731 (October 13, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22249.pdf
P-17-0266	Alcohols, C12-13-branched and linear, dimerized	2041102-78-5	Sasol Chemicals (USA) LLC	March 22, 2017	March 22, 2017	July 27, 2017	127	127	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 26681 (June 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-06-08/pdf/2017-11933.pdf	82 FR 47731 (October 13, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22249.pdf
P-17-0264	Alkanoic acid, 2-alkyl-, substituted alkyl ester, polymer with alkyl alkenoate, substituted carbomonocycle, substituted alkyl alkenoate and alkyl substituted alkenoate, substituted alkanenitrile-initiated	Not available	Allnex USA Inc	March 22, 2017	March 22, 2017	June 29, 2017	99	99	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	82 FR 26681 (June 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-06-08/pdf/2017-11933.pdf	82 FR 37215 (August 9, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-08-09/pdf/2017-16824.pdf
P-17-0255	Carbomonocyclic dicarboxylic acid, polymer with carbomonocyclic dicarboxylic acid, alkanedioic acid, alkenedioic acid, substituted dioxoheteropolycyclic, substituted dioxoheteropolycyclic, alkanedioic acid, alkoxylated alkylidene dicarbomonocycle and alkoxylated alkylidene dicarbomonocycle, ester	Not available	KAO Specialties Americas LLC	March 14, 2017	March 14, 2017	June 7, 2017	85	85	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 26681 (June 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-06-08/pdf/2017-11933.pdf	82 FR 37215 (August 9, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-08-09/pdf/2017-16824.pdf
P-17-0256	Carbopolycyclic dicarboxylic acid, dialkyl ester, polymer with dialkyl carbomonocyclic diester, dialkyl substituted carbomonocyclic diester alkali metal salt and alkanediol	Not available	KAO Specialties Americas LLC	March 14, 2017	March 14, 2017	May 18, 2017	65	65	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	82 FR 26681 (June 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-06-08/pdf/2017-11933.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf
P-17-0246	Polycarbonate polyol	Not available	CBI	February 28, 2017	February 28, 2017	May 11, 2017	72	72	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 21996 (May 11, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-05-11/pdf/2017-09559.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf
P-17-0237	1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6E)-, homopolymer, hydrogenated, 2-hydroxyethyl-terminated	2007163-33-7	CBI	February 23, 2017	February 23, 2017	May 19, 2017	85	85	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 21996 (May 11, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-05-11/pdf/2017-09559.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf
P-17-0238	1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6E)-, homopolymer, 2-hydroxypropyl-terminated, hydrogenated	1912453-88-3	CBI	February 23, 2017	February 23, 2017	May 19, 2017	85	85	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 21996 (May 11, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-05-11/pdf/2017-09559.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf
P-17-0014	Fatty acids, C8-10, mixed esters with C18-unsatd. fatty acid dimers and .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl)	None	Santolubes Manufacturing Llc	February 10, 2017	February 6, 2017	March 13, 2017	31	35	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 21996 (May 11, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-05-11/pdf/2017-09559.pdf	82 FR 31060 (July 5, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-05/pdf/2017-14084.pdf
P-17-0227	2-Alkenoic acid, 2-alkyl-, alkyl ester, polymer with 2-alkyl 2-propenoate and -(2-alkyl-1-oxo-2-alken-1-yl--alkoxypoly(oxy-1,2-alkanediyl), ester with -2-alken-1-yl--hydroxypoly(oxy-1,2-alkanediyl)	Not available	CBI	February 1, 2017	February 1, 2017	April 27, 2017	85	85	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	82 FR 21996 (May 11, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-05-11/pdf/2017-09559.pdf	82 FR 35944 (August 2, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-08-02/pdf/2017-16275.pdf
P-17-0219	Polyester of aliphatic glycols and aromatic diacids	Not available	CBI	January 27, 2017	January 1, 2017	July 14, 2017	168	194	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	82 FR 13992 (March 16, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05287.pdf	82 FR 47731 (October 13, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22249.pdf
P-17-0207	2-alkenoic acid, 2 alkyl, 2 alkyl ester, polymer with alkyl alkenoate, carbomonocyle, alkyl alkenoate and alkyl alkenoate, alkyl peroxide initiated	Not available	CBI	January 23, 2017	January 1, 2017	May 18, 2017	115	137	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	82 FR 13992 (March 16, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05287.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf

P-16-0592	Fatty acids, C8-10, diesters with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl)	None	Santolubes Manufacturing, LLC	January 23, 2017	January 23, 2017	March 13, 2017	49	49	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 13992 (March 16, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05287.pdf	82 FR 31060 (July 5, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-05/pdf/2017-14084.pdf
P-17-0215	Copolymer of alpha-olefin and dibutyl maleate	Not available	Clariant Corporation	January 16, 2017	January 16, 2017	March 13, 2017	56	56	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 13992 (March 16, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05287.pdf	82 FR 31060 (July 5, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-05/pdf/2017-14084.pdf
P-17-0214	2-Propenoic acid, polymer with alkene and alkenyl acetate, alkyl 2-alkyl isoalkyl esters	Not available	Clariant Corporation	January 16, 2017	January 16, 2017	March 13, 2017	56	56	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 13992 (March 16, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05287.pdf	82 FR 31060 (July 5, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-05/pdf/2017-14084.pdf
P-17-0194	Hydrogenated dihalo dialkyl diindolotriphenodioxazine, dihydrodisubstituted isoindolyl alkyl derivs	Not available	CBI	January 4, 2017	January 1, 2017	March 13, 2017	68	71	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 13992 (March 16, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05287.pdf	82 FR 31060 (July 5, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-05/pdf/2017-14084.pdf
P-17-0190	Butanoic acid, 3-oxo-, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl ester, polymer with cycloalkyl 2-methyl-2-propenoate, ethenylbenzene, 2-ethylhexyl 2- propenoate, methyl 2-methyl-2-propenoate and 2-methylpropyl 2-methyl-2-propenoate	Not available	CBI	December 26, 2016	December 26, 2016	September 6, 2017	254	254	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 13339 (March 10, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-10/pdf/2017-04772.pdf	Information not found
P-17-0185	Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with C18-unsatd. fatty acid trimers, alkylenediamine and hydroxyalkanoic acid	Not available	CBI	December 20, 2016	December 30, 2016	February 13, 2017	55	45	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	82 FR 13339 (March 10, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-10/pdf/2017-04772.pdf	82 FR 19046 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08246.pdf
P-17-0158	Perylene bisimide	Not available	Dayglo Color Corp	November 30, 2016	November 30, 2016	February 13, 2017	75	75	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 91162 (December 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-12-16/pdf/2016-30325.pdf	82 FR 19046 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08246.pdf
P-17-0144	Amines, C36-alkylenedi-, polymers with octahydro-4,7-methano-1H-indenedimethanamine and pyromellitic dianhydride, maleated	2020378-57-6	CBI	November 18, 2016	November 18, 2016	January 18, 2017	61	61	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 91162 (December 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-12-16/pdf/2016-30325.pdf	82 FR 19046 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08246.pdf
P-17-0117	1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6E)-, homopolymer, 2-hydroxypropyl-terminated	1898242-86-8	CBI	November 17, 2016	November 17, 2016	July 24, 2017	249	249	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	81 FR 91162 (December 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-12-16/pdf/2016-30325.pdf	82 FR 47731 (October 13, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22249.pdf
P-17-0118	1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6E)-, homopolymer, 2-hydroxyethyl-terminated	2007163-32-6	CBI	November 17, 2016	November 17, 2016	July 24, 2017	249	249	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	81 FR 91162 (December 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-12-16/pdf/2016-30325.pdf	82 FR 47731 (October 13, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22249.pdf
P-17-0112	1,4-Benzenedicarboxylic acid, polymer with hexanedioic acid and 1,6-hexanediol	84191-80-0	CBI	November 16, 2016	November 11, 2016	July 6, 2017	232	237	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	81 FR 91162 (December 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-12-16/pdf/2016-30325.pdf	82 FR 47731 (October 13, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22249.pdf
P-17-0008	Modified 1,3-isobenzofurandione, polymer with 1,2-ethanediol, 2-ethyl-2-(alkoxyalkyl)-1,3-propanediol and 1,3-Isobenzofurandione, alkanoate	Not available	CBI	November 2, 2016	November 2, 2016	March 30, 2017	148	148	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 91162 (December 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-12-16/pdf/2016-30325.pdf	82 FR 31060 (July 5, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-05/pdf/2017-14084.pdf
P-17-0016	Hydroxyl alkyl acrylate ester, polymer with acrylates, aromatic vinyl monomer, cycloaliphatic lactone, and alkyl carboxylic acid, peroxide initiated	Not available	CBI	October 27, 2016	October 25, 2016	December 19, 2016	53	55	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 19044 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08250.pdf

P-17-0017	Hydroxyl alkyl acrylate ester, polymer with acrylates, aromatic vinyl monomer, cycloaliphatic lactone, and alkyl carboxylic acid, peroxide initiated	Not available	CBI	October 27, 2016	October 25, 2016	December 19, 2016	53	55	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 19044 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08250.pdf
P-17-0018	Hydroxyl alkyl acrylate ester, polymer with acrylates, aromatic vinyl monomer, cycloaliphatic lactone, and alkyl carboxylic acid, Azobis[aliphatic nitrile] initiated	Not available	CBI	October 27, 2016	October 25, 2016	December 19, 2016	53	55	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 19044 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08250.pdf
P-17-0019	Hydroxyl alkyl acrylate ester, polymer with acrylates, aromatic vinyl monomer, cycloaliphatic lactone, and alkyl carboxylic acid, peroxide initiated	Not available	CBI	October 27, 2016	October 25, 2016	December 19, 2016	53	55	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 19044 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08250.pdf
P-17-0020	Hydroxyl alkyl acrylate ester, polymer with acrylates, aromatic vinyl monomer, cycloaliphatic lactone, and alkyl carboxylic acid, peroxide initiated	Not available	CBI	October 27, 2016	October 25, 2016	December 19, 2016	53	55	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 19044 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08250.pdf
P-17-0021	Hydroxyl alkyl acrylate ester, polymer with acrylates, aromatic vinyl monomer, cycloaliphatic lactone, and alkyl carboxylic acid, Azobis[aliphatic nitrile] initiated	Not available	CBI	October 27, 2016	October 25, 2016	December 19, 2016	53	55	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 19044 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08250.pdf
P-16-0578	Alkenoic acid, alkyester, polymer with N-(dialkyl-oxoalkyl)-alkenamide, alkenylbenzene, alkyl alkenoate and alkenoic acid	Not available	CBI	October 21, 2016	September 18, 2016	May 15, 2017	206	239	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf
P-17-0009	Depolymerized waste plastics	Not available	CBI	October 13, 2016	October 13, 2016	December 1, 2016	49	49	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf	82 FR 19044 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08250.pdf
P-16-0587	Galactoarabinoxylan	37324-70-2	Kemira Chemicals	September 22, 2016	September 22, 2016	June 15, 2017	266	266	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 79020 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27195.pdf	82 FR 37215 (August 9, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-08-09/pdf/2017-16824.pdf
P-16-0588	Alkyl methacrylate, polymer with alkyl acrylate and polyesters	Not available	CBI	September 22, 2016	September 22, 2016	May 30, 2017	250	250	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	81 FR 79020 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27195.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf
P-16-0580	Trimethylolpropane ester of mixed linear and branched carboxylic acids	Not available	CBI	September 19, 2016	September 19, 2016	November 10, 2016	52	52	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 79020 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27195.pdf	82 FR 9740 (February 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-02-08/pdf/2017-02596.pdf
P-16-0545	Substituted siloxane polymer	Not available	CBI	September 2, 2016	September 2, 2016	November 10, 2016	69	69	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 79020 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27195.pdf	82 FR 9740 (February 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-02-08/pdf/2017-02596.pdf
P-16-0519	Polyalkylether polyester	Not available	CBI	August 12, 2016	August 12, 2016	November 17, 2016	97	97	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 79013 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27193.pdf	82 FR 9740 (February 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-02-08/pdf/2017-02596.pdf
P-16-0518	Polyalkylether polyester	Not available	CBI	August 12, 2016	August 12, 2016	November 17, 2016	97	97	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 79013 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27193.pdf	82 FR 9740 (February 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-02-08/pdf/2017-02596.pdf

P-16-0515	Diamine substituted arylimidazole	Not available	CBI	August 9, 2016	August 9, 2016	November 10, 2016	93	93	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 79013 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27193.pdf	82 FR 9740 (February 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-02-08/pdf/2017-02596.pdf
P-16-0492	Polyester-amide polymer of 'isophthalic acid' with diamino-alkane, cyclohexanedialcohol, alkanetriol, di-isocyanate and acrylic acid-ethylene copolymer	Not available	CBI	July 27, 2016	July 25, 2016	November 10, 2016	106	108	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 57903 (August 24, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20303.pdf	82 FR 9740 (February 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-02-08/pdf/2017-02596.pdf
P-16-0459	Carbomonocyclic dicarboxylic acid, polymer with alkanedioic acid, substituted heteropolycycle, substituted carbomonocycle, alkyl alkenoate, alkanedioic acid, alkoxylated substituted dicarbomonocycle, alkoxylated substituted dicarbomonocycle, alkenoic acid, oxo alkyl initiated	Not available	CBI	July 14, 2016	July 8, 2016	October 4, 2016	82	88	The chemical substances are not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. Although EPA estimated that the new chemical substances would be very persistent, this did not indicate a likelihood that the chemical substances would present an unreasonable risk, given that the chemical substances have low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 57903 (August 24, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20303.pdf	81 FR 80662 (November 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-16/pdf/2016-27545.pdf
P-16-0466	2,5-Furandione, telomer with ethenylbenzene and (alkylethyl)benzene, amides with polyethylene-polypropylene glycol aminoalkyl Me ether, alkali salts	Not available	CBI	July 11, 2016	July 11, 2016	September 2, 2016	53	53	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental toxicity. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 57903 (August 24, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20303.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0426	Alkenyl bis-succinimide	Not available	CBI	June 22, 2016	June 30, 2016	June 28, 2017	371	363	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf	82 FR 37215 (August 9, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-08-09/pdf/2017-16824.pdf
P-16-0401	Alkyl acrylate polymer	Not available	CBI	June 22, 2016	June 22, 2016	June 15, 2017	358	358	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf	82 FR 37215 (August 9, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-08-09/pdf/2017-16824.pdf
P-16-0403	Heteropolycyclic carboxylic acid, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol and 4-substitutedbenzene, substituted carbomonocycle- and alkyl-substituted carbomonocycle-blocked	Not available	CBI	June 15, 2016	June 22, 2016	November 17, 2016	155	148	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 49976 (July 29, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-18015.pdf	82 FR 9740 (February 8, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-02-08/pdf/2017-02596.pdf
P-16-0392	Modified vegetable oil	Not available	CBI	May 25, 2016	June 22, 2016	July 29, 2016	65	37	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental toxicity. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0391	Polyester polyol polymer with aliphatic isocyanate and phenol derivates	Not available	CBI	May 23, 2016	June 22, 2016	September 14, 2016	114	84	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0373	Tris(alkyloxyphenyl)triazine compounds	Not available	CBI	May 13, 2016	June 22, 2016	September 12, 2016	122	82	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0366	Blocked polyisocyanate	Not available	CBI	May 11, 2016	June 22, 2016	September 12, 2016	124	82	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0348	Polypentaerythritol, mixed esters with linear and branched monoacids	Not available	CBI	May 7, 2016	June 22, 2016	September 2, 2016	118	72	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf

P-16-0351	Glycerides, C14-18 and C16-C18 unsaturated, from fermentation	Not available	Solazyme, Inc	May 2, 2016	June 22, 2016	July 29, 2016	88	37	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental toxicity. Although EPA estimated that the new chemical substance would be persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0343 and P-16-0344	Modified urethane polymer	Not available	CBI	April 27, 2016	June 22, 2016	September 16, 2016	142	86	The chemical substances are not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. Although EPA estimated that the new chemical substances would be very persistent, this did not indicate a likelihood that the chemical substances would present an unreasonable risk, given that the chemical substances have low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0340	Glycerides, C8-18 and C18 unsaturated, from fermentation	Not available	Solazyme, Inc	April 26, 2016	June 22, 2016	July 29, 2016	94	37	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental toxicity. Although EPA estimated that the new chemical substance would be persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0281	Fatty alcohols-dimers, trimers, polymers	Not available	CBI	April 11, 2016	June 22, 2016	July 15, 2016	72	23	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0303	Alkyl methyacrylate polymer with styrene, amino acrylate and acrylic acid, ammonium salt	Not available	CBI	April 7, 2016	June 22, 2016	May 30, 2017	418	342	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C). The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 CFR §723.250(e)(1), in addition to meeting the definition of polymer at 40 CFR §723.250(b).	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf	82 FR 34942 (July 27, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15735.pdf
P-16-0302	Organic modified propyl silsesquioxane	Not available	CBI	April 6, 2016	June 22, 2016	July 20, 2016	77	28	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental toxicity. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0301	Propyl silsesquioxanes, hydrogen-terminated	Not available	CBI	April 6, 2016	June 22, 2016	July 20, 2016	77	28	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-16-0292	Depolymerized waste plastics	Not available	CBI	April 5, 2016	June 22, 2016	July 20, 2016	78	28	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard. TSCA section 5(a)(3)(C).	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf	81 FR 65636 (September 23, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22972.pdf
P-14-0314	Poly aliphatic phosphate	Not available	CBI	February 7, 2014	June 22, 2016	July 31, 2017	1270	404	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf	82 FR 47731 (October 13, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22249.pdf
P-17-0390	Carbomonocyclic dicarboxylic acid, polymer with alkenedioic acid, substituted heteropolycycle, substituted heteromonocycle, alkanediol, alkanedioic acid, alkoxylated substituted dicarbomonocycle, alkoxylated substituted dicarbomonocycle and alkanetriol, carbomonocyclic carboxylate alkanoate	Not available	Information not found	N/A	September 6, 2017	November 2, 2017	N/A	57	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	Information not found	Information not found
P-17-0160	2-Propenoic acid, alkyl-, alkyl ester, polymer with alkyl 2-propenoate, dialkyloxoalkyl-2-propenamide and alkyl 2-propenoate. Generic: 2-Propenoic acid, alkyl-, alkyl ester, polymer with alkyl 2-propenoate, dialkyloxoalkyl-2-propenamide, ethenylbenzene and alkyl 2-propenoate	Not available	Information not found	N/A	November 13, 2016	February 13, 2017	N/A	92	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	Information not found	82 FR 19046 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08246.pdf
P-17-0182	Alkyldioic acid, polymer with 2,2-dimethyl-1,3-propanediol, heteropolycyclic carboxy acid anhydride and 1,3-propanediol	Not available	Information not found	N/A	December 30, 2016	February 12, 2017	N/A	44	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	Information not found	82 FR 19046 (April 25, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-25/pdf/2017-08246.pdf

P-16-0508	Terephthalic acid and alcohol ester polymer hydroxy glycol and 2-Ethylhexyl alcohol	Not available	Information not found	N/A	October 4, 2016	September 26, 2017	N/A	357	The chemical substance is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard. TSCA section 5(a)(3)(C).	Information not found	Information not found

PMN #	Chemical Name	CAS Number	PMN Submitter Name	Date PMN Filed	Effective Date of 5(e) Order	Number of Days to 5(e) Order from Submission of the PMN	Date NOC Received	Number of Days to NOC from Submission of the PMN	Date of EPA Initiation of SNUR Rulemaking	Number of Days to EPA Initiation of Rulemaking from Effective Date of 5(e) Order	Effective Date of Direct Final SNUR	Number of Days to Effective Date of Direct Final SNUR from Submission of the PMN	Adverse Comments on the Direct Final SNUR (Y/N)	Date of Proposed SNUR (if Y to previous)	Date of Final SNUR	Basis for Action	Testing	SNUR CFR Citation and Federal Register Citation and Link	PMN Notice Federal Register Citation and Link
P-15-310	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters	Not available	Sasol Chemicals (USA), LLC	February 23, 2015 (Reissued June 22, 2016)	January 31, 2017	708	N/A	N/A	October 19, 2017	261	December 18, 2017 (If no adverse comments received)	1029 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substance will be used as a lubricant in special chain oils for conveyor belts. Based on submitted test data, EPA predicts blood and adrenal gland effects to unprotected workers from repeated dermal exposures. EPA also predicts endocrine disruption based on Structure Activity Relationship (SAR) analysis on analogous phthalates. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended Testing: EPA has determined that the results of certain human health toxicity testing would help characterize the PMN substance. The submitter has agreed not to exceed the confidential production limit without performing an Extended One-Generation Reproductive Toxicity Study (OECD Test Guideline 443).	40 CFR 721.10996 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-487	Multi-walled carbon nanotubes (generic)	Not available	Daewoo International USA Corp	May 22, 2015 (Reissued June 22, 2016)	February 17, 2017	637	April 12, 2017	691	October 19, 2017	244	December 18, 2017 (If no adverse comments received)	941 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as additives for electro-static discharge (ESD) in electronic devices, electronics, and materials; additives for weight reduction in materials; additives to improve mechanical properties or electrical conductivities; heat-generating elements in heating devices and materials; additives for heat transfer and thermal emissions in electronic devices and materials; semi-conductor, conductive, or resistive elements in electronic circuitry and devices; additives to improve conductivity in electronic circuitry, energy storage systems, and devices; electron-emitters for lighting and x-ray sources; additive for electromagnetic interface shielding in electronic devices; additives for electrodes in electronic materials and electronic devices; catalyst support in chemical manufacturing; coating additives to improve corrosion resistance or conductive properties; additives for fibers in structural and electrical applications; additives for fibers in fabrics and textiles; filter additives to remove nanoscale materials; semi-conducting compounding additives for high-voltage cable; and additives for super-hydrophobicity. A submitted 90-day inhalation toxicity study for P-15-487 demonstrated no effects at 1 mg/m3, which was the highest dose tested. Based on SAR analysis on analogous carbon nanotubes (CNT), EPA predicts pulmonary toxicity and oncogenicity to unprotected workers from repeated inhalation exposures. No ecotoxicity studies on CNT are available in which a broad range of production methods, sources, purification, functionalization, etc. were investigated. EPA expects that some fraction of the PMN substances, if released into the environment, will eventually become suspended in water. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that a subchronic 90-day inhalation toxicity study (OPPTS 870.3465 or OECD 413), a two-year inhalation bioassay (OPPTS 870.4200), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10997 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	80 FR 37248 (June 30, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-30/pdf/2015-16047.pdf
P-15-488	Multi-walled carbon nanotubes (generic)	Not available	Daewoo International USA Corp	May 22, 2015 (Reissued June 22, 2016)	February 17, 2017	637	April 12, 2017	691	October 19, 2017	244	December 18, 2017 (If no adverse comments received)	941 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as additives for electro-static discharge (ESD) in electronic devices, electronics, and materials; additives for weight reduction in materials; additives to improve mechanical properties or electrical conductivities; heat-generating elements in heating devices and materials; additives for heat transfer and thermal emissions in electronic devices and materials; semi-conductor, conductive, or resistive elements in electronic circuitry and devices; additives to improve conductivity in electronic circuitry, energy storage systems, and devices; electron-emitters for lighting and x-ray sources; additive for electromagnetic interface shielding in electronic devices; additives for electrodes in electronic materials and electronic devices; catalyst support in chemical manufacturing; coating additives to improve corrosion resistance or conductive properties; additives for fibers in structural and electrical applications; additives for fibers in fabrics and textiles; filter additives to remove nanoscale materials; semi-conducting compounding additives for high-voltage cable; and additives for super-hydrophobicity. A submitted 90-day inhalation toxicity study for P-15-487 demonstrated no effects at 1 mg/m3, which was the highest dose tested. Based on SAR analysis on analogous carbon nanotubes (CNT), EPA predicts pulmonary toxicity and oncogenicity to unprotected workers from repeated inhalation exposures. No ecotoxicity studies on CNT are available in which a broad range of production methods, sources, purification, functionalization, etc. were investigated. EPA expects that some fraction of the PMN substances, if released into the environment, will eventually become suspended in water. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that a subchronic 90-day inhalation toxicity study (OPPTS 870.3465 or OECD 413), a two-year inhalation bioassay (OPPTS 870.4200), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10997 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	80 FR 37248 (June 30, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-30/pdf/2015-16047.pdf
P-15-489	Multi-walled carbon nanotubes (generic)	Not available	Daewoo International USA Corp	May 22, 2015 (Reissued June 22, 2016)	February 17, 2017	637	April 12, 2017	691	October 19, 2017	244	December 18, 2017 (If no adverse comments received)	941 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as additives for electro-static discharge (ESD) in electronic devices, electronics, and materials; additives for weight reduction in materials; additives to improve mechanical properties or electrical conductivities; heat-generating elements in heating devices and materials; additives for heat transfer and thermal emissions in electronic devices and materials; semi-conductor, conductive, or resistive elements in electronic circuitry and devices; additives to improve conductivity in electronic circuitry, energy storage systems, and devices; electron-emitters for lighting and x-ray sources; additive for electromagnetic interface shielding in electronic devices; additives for electrodes in electronic materials and electronic devices; catalyst support in chemical manufacturing; coating additives to improve corrosion resistance or conductive properties; additives for fibers in structural and electrical applications; additives for fibers in fabrics and textiles; filter additives to remove nanoscale materials; semi-conducting compounding additives for high-voltage cable; and additives for super-hydrophobicity. A submitted 90-day inhalation toxicity study for P-15-487 demonstrated no effects at 1 mg/m3, which was the highest dose tested. Based on SAR analysis on analogous carbon nanotubes (CNT), EPA predicts pulmonary toxicity and oncogenicity to unprotected workers from repeated inhalation exposures. No ecotoxicity studies on CNT are available in which a broad range of production methods, sources, purification, functionalization, etc. were investigated. EPA expects that some fraction of the PMN substances, if released into the environment, will eventually become suspended in water. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that a subchronic 90-day inhalation toxicity study (OPPTS 870.3465 or OECD 413), a two-year inhalation bioassay (OPPTS 870.4200), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10997 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	80 FR 37248 (June 30, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-30/pdf/2015-16047.pdf
P-15-490	Multi-walled carbon nanotubes (generic)	Not available	Daewoo International USA Corp	May 22, 2015 (Reissued June 22, 2016)	February 17, 2017	637	April 12, 2017	691	October 19, 2017	244	December 18, 2017 (If no adverse comments received)	941 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as additives for electro-static discharge (ESD) in electronic devices, electronics, and materials; additives for weight reduction in materials; additives to improve mechanical properties or electrical conductivities; heat-generating elements in heating devices and materials; additives for heat transfer and thermal emissions in electronic devices and materials; semi-conductor, conductive, or resistive elements in electronic circuitry and devices; additives to improve conductivity in electronic circuitry, energy storage systems, and devices; electron-emitters for lighting and x-ray sources; additive for electromagnetic interface shielding in electronic devices; additives for electrodes in electronic materials and electronic devices; catalyst support in chemical manufacturing; coating additives to improve corrosion resistance or conductive properties; additives for fibers in structural and electrical applications; additives for fibers in fabrics and textiles; filter additives to remove nanoscale materials; semi-conducting compounding additives for high-voltage cable; and additives for super-hydrophobicity. A submitted 90-day inhalation toxicity study for P-15-487 demonstrated no effects at 1 mg/m3, which was the highest dose tested. Based on SAR analysis on analogous carbon nanotubes (CNT), EPA predicts pulmonary toxicity and oncogenicity to unprotected workers from repeated inhalation exposures. No ecotoxicity studies on CNT are available in which a broad range of production methods, sources, purification, functionalization, etc. were investigated. EPA expects that some fraction of the PMN substances, if released into the environment, will eventually become suspended in water. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that a subchronic 90-day inhalation toxicity study (OPPTS 870.3465 or OECD 413), a two-year inhalation bioassay (OPPTS 870.4200), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10997 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	80 FR 37248 (June 30, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-30/pdf/2015-16047.pdf
P-15-491	Multi-walled carbon nanotubes (generic)	Not available	Daewoo International USA Corp	May 22, 2015 (Reissued June 22, 2016)	February 17, 2017	637	April 12, 2017	691	October 19, 2017	244	December 18, 2017 (If no adverse comments received)	941 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as additives for electro-static discharge (ESD) in electronic devices, electronics, and materials; additives for weight reduction in materials; additives to improve mechanical properties or electrical conductivities; heat-generating elements in heating devices and materials; additives for heat transfer and thermal emissions in electronic devices and materials; semi-conductor, conductive, or resistive elements in electronic circuitry and devices; additives to improve conductivity in electronic circuitry, energy storage systems, and devices; electron-emitters for lighting and x-ray sources; additive for electromagnetic interface shielding in electronic devices; additives for electrodes in electronic materials and electronic devices; catalyst support in chemical manufacturing; coating additives to improve corrosion resistance or conductive properties; additives for fibers in structural and electrical applications; additives for fibers in fabrics and textiles; filter additives to remove nanoscale materials; semi-conducting compounding additives for high-voltage cable; and additives for super-hydrophobicity. A submitted 90-day inhalation toxicity study for P-15-487 demonstrated no effects at 1 mg/m3, which was the highest dose tested. Based on SAR analysis on analogous carbon nanotubes (CNT), EPA predicts pulmonary toxicity and oncogenicity to unprotected workers from repeated inhalation exposures. No ecotoxicity studies on CNT are available in which a broad range of production methods, sources, purification, functionalization, etc. were investigated. EPA expects that some fraction of the PMN substances, if released into the environment, will eventually become suspended in water. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that a subchronic 90-day inhalation toxicity study (OPPTS 870.3465 or OECD 413), a two-year inhalation bioassay (OPPTS 870.4200), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10997 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	80 FR 37248 (June 30, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-30/pdf/2015-16047.pdf
P-16-165	Propanoic acid, iron (2+) salt (2:1)	1952336-63-8	Dura Chemicals, Inc	February 19, 2016 (Reissued June 22, 2016 and July 26, 2016)	February 15, 2017	362	N/A	N/A	October 19, 2017	246	December 18, 2017 (If no adverse comments received)	668 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substance will be used as a component in a metal organic product that will be used in paint and ink driers, unsaturated polyester resins promoters, lube/grease additives, fuel additives, polymerization catalysts, and specialty petrochemical catalysts at less than 1 percent. Based on submitted test data, EPA predicts liver and developmental toxicity to unprotected workers from repeated inhalation exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended Testing: EPA has determined that the results of certain human health toxicity testing would help characterize the PMN substance. The submitter has agreed not to exceed the confidential production limit without performing the prenatal development toxicity study (OECD 414). In addition, EPA has determined that the results of a combined chronic toxicity and carcinogenicity toxicity test (OPPTS 870.4300) would help characterize the health effects of the PMN substance. The Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10998 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 20633 (April 8, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08135.pdf
P-16-255	1-Butanaminium, N,N,N-tributyl-, carbonic acid (1:1)	17351-62-1	CBI	June 22, 2016	March 7, 2017	258	May 4, 2017	316	October 19, 2017	226	December 18, 2017 (If no adverse comments received)	544 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as blocked catalysts for paints and coatings. Based on submitted test data, EPA predicts strong irritation to the skin, eyes, and mucous membranes as well as acute toxicity and corrosivity-related neurotoxicity from repeated dermal and inhalation exposures. Further, based on test data on the PMN substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 parts per billion (ppb) of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that the results of certain environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a daphnid chronic toxicity test (OCSPP 850.1300).	40 CFR 721.10999 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-256	1-Butanaminium, N,N,N-tributyl-, methyl carbonate (1:1)	56294-05-2	CBI	June 22, 2016	March 7, 2017	258	May 4, 2017	316	October 19, 2017	226	December 18, 2017 (If no adverse comments received)	544 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as blocked catalysts for paints and coatings. Based on submitted test data, EPA predicts strong irritation to the skin, eyes, and mucous membranes as well as acute toxicity and corrosivity-related neurotoxicity from repeated dermal and inhalation exposures. Further, based on test data on the PMN substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 parts per billion (ppb) of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that the results of certain environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a daphnid chronic toxicity test (OCSPP 850.1300).	40 CFR 721.10999 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-257	1-Butanaminium, N,N,N-tributyl-, ethyl carbonate (1:1)	478796-04-2	CBI	June 22, 2016	March 7, 2017	258	May 4, 2017	316	October 19, 2017	226	December 18, 2017 (If no adverse comments received)	544 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as blocked catalysts for paints and coatings. Based on submitted test data, EPA predicts strong irritation to the skin, eyes, and mucous membranes as well as acute toxicity and corrosivity-related neurotoxicity from repeated dermal and inhalation exposures. Further, based on test data on the PMN substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 parts per billion (ppb) of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that the results of certain environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a daphnid chronic toxicity test (OCSPP 850.1300).	40 CFR 721.11000 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-258	1-Butanaminium, N,N,N-tributyl-, propyl carbonate (1:1)	1338579-13-7	CBI	June 22, 2016	March 7, 2017	258	May 4, 2017	316	October 19, 2017	226	December 18, 2017 (If no adverse comments received)	544 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as blocked catalysts for paints and coatings. Based on submitted test data, EPA predicts strong irritation to the skin, eyes, and mucous membranes as well as acute toxicity and corrosivity-related neurotoxicity from repeated dermal and inhalation exposures. Further, based on test data on the PMN substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 parts per billion (ppb) of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that the results of certain environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a daphnid chronic toxicity test (OCSPP 850.1300).	40 CFR 721.11001 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-259	1-Butanaminium, N,N,N-tributyl-, and 1-methylethyl carbonate (1:1)	1803407-49-9	CBI	June 22, 2016	March 7, 2017	258	May 4, 2017	316	October 19, 2017	226	December 18, 2017 (If no adverse comments received)	544 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as blocked catalysts for paints and coatings. Based on submitted test data, EPA predicts strong irritation to the skin, eyes, and mucous membranes as well as acute toxicity and corrosivity-related neurotoxicity from repeated dermal and inhalation exposures. Further, based on test data on the PMN substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 parts per billion (ppb) of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended Testing: EPA has determined that the results of certain environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a daphnid chronic toxicity test (OCSPP 850.1300).	40 CFR 721.11003 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-284	Aniline substituted bis-triazinyl derivative of 4,4'-diaminostilbene-2,2'-disulfonic acid, mixed amine sodium salt (generic)	Not available	Deepak Nitrite (D) Corporation, Inc	March 29, 2016 (Reissued June 22, 2016 & January 11, 2017)	May 12, 2017	409	February 12, 2017	320	October 19, 2017	160	December 18, 2017 (If no adverse comments received)	629 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substance will be used as an optical brightener for textiles, paper, and paperboard. Based on submitted test data, EPA predicts adrenal gland effects to unprotected workers from repeated dermal and inhalation exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended Testing: EPA has determined that the results of physical/chemistry testing would help characterize the PMN substance. The submitter has agreed not to manufacture beyond a certain time period without measuring the particle size distribution to characterize the particle size distribution of fractions less than 10 microns of the dry particle PMN substance. In addition, EPA has determined that the results of a 90-day subchronic inhalation toxicity study (OPPTS 870.3465 or OECD 413) would help characterize the health effects of the PMN substance. The Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.11004 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	82 FR 13992 (March 16, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05287.pdf
P-16-309	12-hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (generic)	Not available	CBI	April 8, 2016 (Reissued June 22, 2016 and January 13, 2017)	February 17, 2017	315	N/A	N/A	October 19, 2017	244	December 18, 2017 (If no adverse comments received)	619 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PMN states that the PMN substances will be used as rheological or thixotropic agents used in the production of solvent based industrial coatings, high solid aromatic paints, adhesives, sealants, and other types of paints and topcoats. Based on submitted test data, EPA predicts blood and hematology effects. Further, based on SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the results of certain human health and environmental toxicity testing would help characterize the PMN substances. The submitter has agreed not to exceed the confidential production limit without performing a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.1300). In addition, EPA has determined that the results of a repeated dose dermal toxicity test (OPPTS Test Guideline 870.3200) would help characterize the human health effects of the PMN substances. The Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.11005 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf

P-16-310	12-hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (generic)	Not available	CBI	April 8, 2016 (Reissued June 22, 2016 and January 13, 2017)	February 17, 2017	315	N/A	N/A	October 19, 2017	244	December 18, 2017 (If no adverse comments received)	619 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substances will be used as rheological or thixotropic agents used in the production of solvent based industrial coatings, high solid aromatic paints, adhesives, sealants, and other types of paints and topcoats. Based on submitted test data, EPA predicts blood and hematology effects. Further, based on SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PVN substances in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the results of certain human health and environmental toxicity testing would help characterize the PVN substances. The submitter has agreed not to exceed the confidential production limit without performing a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.1300). In addition, EPA has determined that the results of a repeated dose dermal toxicity test (OPPTS Test Guideline 870.3200) would help characterize the human health effects of the PVN substances. The Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.11005 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf
P-16-315	Alkyldiene, polymer, hydroxy terminated alkoxysilylalkylcarbamate (generic)	Not available	CBI	April 11, 2016 (Reissued June 22, 2016, January 11, 2017 and March 29, 2017)	January 17, 2017	281	July 17, 2017	462	October 19, 2017	275	December 18, 2017 (If no adverse comments received)	636 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as an additive to improve the compatibility of the dispersibility of inorganic fillers in industrial rubber formulation. Based on physical/chemical properties, EPA predicts irritation and lung effects to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(2)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that a 90-day subchronic inhalation test in rodents (OCSPP Harmonized Test Guideline 870.3465); would help characterize possible health effects of the substance. Although the Order does not require this test, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.11006 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf
P-16-323	Alkylaldehyde, reaction products with substituted carbomonocycle-substituted heteromonocycle-alkylene glycol bis[[[substituted(oxoneoalkyl)oxy]alkyl] amino]alkyl] ether polymer and alkyl substituted alkanediamine, acetate salts (generic)	Not available	Allnex USA, Inc	April 13, 2016 (Reissued May 17, 2016 and June 22, 2016)	November 22, 2016	223	January 3, 2017	265	October 19, 2017	331	December 18, 2017 (If no adverse comments received)	614 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as a coating resin. Based on test data on formaldehyde and analogous cationic polymers, EPA predicts sensitization, carcinogenicity, and lung effects to unprotected workers from repeated dermal exposures. Further, based on SAR analysis of test data on analogous cationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 32 ppb of the PVN substance in surface waters. The Order was issued under TSCA sections 5(a)(2)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that a 28-day subacute inhalation toxicity study (OECD 412), a fish acute toxicity test mitigated by humic acid (OCSPP Test Guideline 850.1085), an aquatic invertebrate, acute toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1075), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.11007 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf
P-16-330	Hydroxy functional triglyceride polymer with glycerol mono-ester and 1,1'-methylenebis[4-isocyanatobenzene]	Not available	H.B. Fuller Company	April 19, 2016 (Reissued June 22, 2016 and October 6, 2016)	February 14, 2017	301	May 1, 2017	377	October 19, 2017	247	December 18, 2017 (If no adverse comments received)	608 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substances will be used as industrial adhesives. Based on submitted test data, EPA predicts dermal sensitization, respiratory sensitization, and lung effects to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that a skin sensitization study (OPPTS 870.2600) and a 90-day inhalation study (OPPTS 870.3465) would help characterize possible health effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.11008 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf
P-16-331	Hydroxy functional triglyceride polymer with glycerol mono-ester and 1,1'-methylenebis[isocyanatobenzene] (P-16-330) (generic)	Not available	H.B. Fuller Company	April 19, 2016 (Reissued June 22, 2016 and October 6, 2016)	February 14, 2017	301	N/A	N/A	October 19, 2017	247	December 18, 2017 (If no adverse comments received)	608 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substances will be used as industrial adhesives. Based on submitted test data, EPA predicts dermal sensitization, respiratory sensitization, and lung effects to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that a skin sensitization study (OPPTS 870.2600) and a 90-day inhalation study (OPPTS 870.3465) would help characterize possible health effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.11009 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 35351 (June 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-06-02/pdf/2016-13028.pdf
P-16-360	Poly(oxy-1,2-ethanediyl),.alpha.-(1-oxodocosyl)-.omega.-[(1-oxodocosyl)oxy]-	36493-27-3	Oleon Americas, Inc	May 12, 2016 (Reissued June 22, 2016)	December 12, 2016	214	N/A	N/A	October 19, 2017	311	December 18, 2017 (If no adverse comments received)	585 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as a fuel additive. Based on physical/chemical properties, EPA estimates the PVN substance would have low environmental hazard due to its poor water solubility. However, if the number of repeating ethylene oxide units in the polymer is large (i.e., greater than 10), the polymer would become a dispersible surfactant. Based on SAR analysis of test data on an analogous nonionic polymer, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 350 ppb of the PVN substance in surface waters. The Order was issued under TSCA sections 5(a)(2)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to the environment.	Recommended testing: EPA has determined that an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010), a fish acute toxicity test, freshwater and marine (OCSPP Test Guideline 850.1075), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible environmental effects of the substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.11010 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-361	Pulp, cellulose, reaction products with lignin	1627062-70-6	American Process Inc	May 12, 2016 (Reissued June 22, 2016)	December 12, 2016	214	N/A	N/A	October 19, 2017	311	December 18, 2017 (If no adverse comments received)	585 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as plastic reinforcement. Based on SAR analysis on structurally similar respirable poorly soluble particulates, EPA predicts pulmonary toxicity to unprotected workers from repeated inhalational exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of physical/chemical characteristics would help characterize the PVN substance. The submitter has agreed not to manufacture beyond a certain time period without measuring the particle size distribution to characterize the particle size distribution of fractions less than 10 microns of the dry particle PMN substance	40 CFR 721.11011 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-365	Alkyl carbonate, polymer with, substituted alkanes and substituted heteromonocycle, substituted alkyl acrylate-blocked (generic)	Not available	Allnex USA, Inc	May 16, 2016 (Reissued June 22, 2016)	January 3, 2017	233	N/A	N/A	October 19, 2017	289	December 18, 2017 (If no adverse comments received)	581 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substances will be used as a UV curable coating resin for industrial use. Based on SAR analysis on structurally similar diisocyanates and acrylates, EPA predicts eye and skin irritation, dermal sensitization, respiratory sensitization, lung effects, mutagenicity, cancer, developmental, liver, and kidney toxicity to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a local lymph node assay (OPPTS 870.2600), a 90-day inhalation toxicity test with 60-day holding period (OPPTS 870.3465), and a two-year oral bioassay (OPPTS 870.4200) would help characterize possible health effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.11012 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf
P-16-367	substituted heteromonocycle, polymer with substituted alkane and ethoxylated alkane, substituted heteromonocycle substituted alkyl ester-blocked (generic) (P-16-367)	Not available	Allnex USA, Inc	May 20, 2016 (Reissued June 22, 2016)	January 3, 2017	228	February 2, 2017	258	October 19, 2017	289	December 18, 2017 (If no adverse comments received)	577 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substances will be used as a UV curable coating resin for industrial use. Based on SAR analysis on structurally similar diisocyanates and acrylates, EPA predicts eye and skin irritation, dermal sensitization, respiratory sensitization, lung effects, mutagenicity, cancer, developmental, liver, and kidney toxicity to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substances may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a local lymph node assay (OPPTS 870.2600), a 90-day inhalation toxicity test with 60-day holding period (OPPTS 870.3465), and a two-year oral bioassay (OPPTS 870.4200) would help characterize possible health effects of the substances. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.11013 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 45148 (July 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16448.pdf
P-16-369	Substituted heteromonocycle, telomer with substituted carbomonocycles, substituted alkyl ester (generic)	Not available	Allnex USA, Inc	May 13, 2016 (Reissued June 22, 2016)	January 23, 2017	255	February 2, 2017	265	October 19, 2017	269	December 18, 2017 (If no adverse comments received)	584 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as a UV curable coating resin for industrial use. Based on SAR analysis on structurally similar acrylates and other chemicals, EPA predicts eye and skin irritation, dermal sensitization, respiratory sensitization, lung effects, mutagenicity, cancer, developmental toxicity, liver, and kidney toxicity to unprotected workers from repeated inhalation and dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of certain human health toxicity testing would help characterize the PVN substance. The submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413). In addition, EPA has determined that the results of a skin sensitization (OPPTS 870.2600), a local lymph node assay (OECD 429), and two-year bioassay (oral) (OPPTS 870.4200) would help characterize possible health effects of the substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.11014 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 https://www.federalregister.gov/documents/2016/10/27/2016-26021/certain-new-chemicals-receipt-and-status-information-for-june-2016
P-16-387	Aliphatic polycarboxylic acid, polymer with aliphatic polyhydric alcohol and polyoxyalkylene (generic)	Not available	CBI	May 31, 2016 (Reissued June 22, 2016 and November 1, 2016)	February 7, 2017	252	March 3, 2017	276	October 19, 2017	254	December 18, 2017 (If no adverse comments received)	566 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as an additive for a polymer. Based on physical/chemical properties of the PVN substance, EPA predicts lung effects to unprotected workers from repeated exposures. The Order was issued under TSCA sections 5(a)(2)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test with 30-day holding period (OPPTS 870.3465), a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD 422) an acute fish toxicity test (OCSPP 850.1075), an acute daphnia toxicity test (OCSPP 850.1300), and an algal toxicity test (OCSPP 850.4500) would help characterize possible health and environmental effects of the substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.11015 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-398	Di-ammonium di-carboxylate (generic)	Not available	CBI	June 6, 2016 (Reissued June 22, 2016)	November 14, 2016	161	November 16, 2016	163	October 19, 2017	339	December 18, 2017 (If no adverse comments received)	560 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as a corrosion inhibitor. Based on test data on analogous anionic surfactants, EPA predicts eye and mucous membrane irritation and skin sensitization to unprotected workers from repeated dermal exposures. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of certain human health toxicity testing would help characterize the effects of the PVN substance. The submitter has agreed not to exceed the confidential production limit without performing three skin sensitization studies (OECD 442B), (OECD 442C), and (OECD 442D).	40 CFR 721.11016 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 74784 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-26021.pdf
P-16-435	Sodium tungsten oxide	Not available	CBI	July 13, 2016	November 2, 2016	113	November 7, 2016	117	October 19, 2017	351	December 18, 2017 (If no adverse comments received)	523 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as a component of infrared absorption material. Based on SAR analysis on structurally similar respirable poorly soluble particulates, EPA predicts pulmonary toxicity and carcinogenicity to unprotected workers from repeated inhalation exposures. Further, based on test data on analogous tungsten oxide, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the results of certain human health toxicity testing would help characterize the PVN substance. The submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) and a two- year inhalation bioassay test (OPPTS 870.4200).	40 CFR 721.11017 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 57903 (August 24, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20303.pdf
P-16-503	Fatty acids, tall-oil, polymers with alkanoic acid, substituted carbomonocycle, alkyl peroxide-initiated (generic)	Not available	Allnex USA Inc.	August 2, 2016	January 11, 2017	163	N/A	N/A	October 19, 2017	281	December 18, 2017 (If no adverse comments received)	504 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as a site-limited polymer intermediate for production of a deck stain coating resin additive. Based on physical/chemical properties, EPA predicts low health hazard for the PVN substance when it is manufactured as described in the PVN. However, if the chemical substance is manufactured with a lower molecular weight and a higher proportion of the acid component (i.e., greater than 20%), the PVN substance could cause developmental effects in unprotected workers from repeated dermal and inhalation exposures. Further, based on physical/chemical properties, EPA predicts low hazard for the PVN substance when it is manufactured as described in the PMN due to low water solubility. However, if the chemical substance is manufactured with a higher proportion of the acid component (i.e., greater than 20%), there is potential for aquatic toxicity. The Order was issued under TSCA sections 5(a)(2)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD 422), water solubility test, log Kow tests, a compositional/component analysis (certificate of analysis), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300), fish acute toxicity mitigated by humic acid (OCSPP Test Guideline 850.1085), an aquatic invertebrate, acute toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1075), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the physical-chemical properties and possible health and environmental effects of the substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.11018 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 79013 (November 10, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-10/pdf/2016-27193.pdf
P-16-591	Alkyl bisphenol (generic)	Not available	CBI	October 4, 2016 (Reissued December 9, 2016)	January 9, 2017	98	N/A	N/A	October 19, 2017	283	December 18, 2017 (If no adverse comments received)	441 (to effective date of direct final SNUR if no adverse comments received)	N/A (comment period open until November 20, 2017)	N/A	N/A (comment period open until November 20, 2017)	The PVN states that the PVN substance will be used as a component of printing ink. Based on test data on bisphenol analogs, EPA predicts irritation to eyes, skin, lung, and mucous membranes; developmental, reproductive, liver and kidney toxicities; dermal sensitization; photosensitization; effects to the adrenals and other toxic effects associated with an endocrine disruption mode of action to unprotected workers from repeated dermal and inhalation exposures. Further, based on SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PVN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(i)(I) and 5(e)(1)(A)(i)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the results of certain human health and environmental toxicity testing would help characterize the PVN substance. The submitter has agreed not to exceed the confidential production limit without performing the reproduction/developmental toxicity screening test (OECD 422). In addition, EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400) and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PVN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.11019 82 FR 48637 (October 19, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-19/pdf/2017-22239.pdf	81 FR 85556 (November 28, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-28/pdf/2016-28568.pdf

P-11-482	Bimodal mixture consisting of multi-walled carbon nanotubes and other classes of carbon nanotubes (generic)	Claimed confidential.	CBI	July 8, 2011	September 30, 2015	1545	N/A	N/A	October 3, 2017	734	N/A (adverse comment received)	N/A	YES The commenter noted a discrepancy between requirements in the consent order and SNUR. While the consent order allows limited surface water releases from the manufacturing process, the draft final SNUR designated as a significant new use any purposeful or predictable releases to surface waters. To make the SNUR consistent with consent order requirements, in this proposed SNUR EPA has designated as a significant new use any predictable or purposeful releases to water from manufacturing, processing, or use other than the water releases described in the PMN for the manufacturing process of P-11-482	Posted: June 8, 2017 Comments Due: July 10, 2017	Posted: October 3, 2017 Effective: November 2, 2017	The PVN states that the generic use of the PVN substance will be as a specialty additive. Based on test data on analogous respirable, poorly soluble particulates and nanocarbon materials, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other nanocarbon materials EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide a dustiness test (European Standard EU 15051) by six months from commencement of manufacture. In addition, the submitter has agreed to provide certain physical-chemical property testing as required in the consent order after the commencement of manufacture. Although the order does not require a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart), a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10927 82 FR 45990 (October 3, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-10-03/pdf/2017-21237.pdf	76 FR 58498 (September 21, 2011) https://www.gpo.gov/fdsys/pkg/FR-2011-09-21/pdf/2011-23973.pdf
P-05-436	Ethylene glycol ester of an aromatic substituted propenoic acid (generic).	Not available	Eastman Chemical Company	March 17, 2005	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	4631	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a modifier for polyester polymer. Based on structure activity relationship (SAR) analysis of test data on structurally similar substances, EPA predicts toxicity to aquatic organisms at concentrations that exceed 10 parts per billion (ppb) of the PVN substance in surface waters. As described in the PVN, releases to surface waters of the PVN substance are not expected to exceed 10 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 10 ppb may cause significant adverse environmental effects.	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (Office of Pollution Prevention and Toxics (OPPTS) Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10961 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	70 FR 19955 (April 15, 2005) https://www.gpo.gov/fdsys/pkg/FR-2005-04-15/pdf/05-7589.pdf
P-10-504	Phosphoric acid, metal salt (generic).	Not available	ICI-IP America Inc.	August 13, 2010	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	2656	No		N/A	N/A	The PVN states that the substance will be used as a flame retardant for textiles. Based on SAR analysis of test data on analogous substances, EPA identified eye and dermal irritation as well as immunotoxicity concerns to workers from exposure to the PVN substance via the inhalation route. Additionally, based on SAR analysis of test data on analogous inorganic phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PVN substance in surface waters. For the use described in the PMN, significant releases of the substance are not expected, and worker dermal and inhalation will be minimal. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that substantial production volume increases, or use of the PVN substance other than as described in the PVN, could change exposure potential, which may cause significant adverse health and environmental effects.	Recommended testing: EPA has determined that the results of a 90-day oral toxicity test (OPPTS Test Guideline 870.3100), a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (Organisation for Economic Co-operation and Development (OECD) Test Guideline 23) be followed to facilitate solubility in the test media.	40 CFR 721.10962 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	75 FR 57770 (September 22, 2010) https://www.gpo.gov/fdsys/pkg/FR-2010-09-22/pdf/2010-23718.pdf
P-13-289	Alkanoic acid, tetramethylheteromonocycle ester (generic).	Not available	CBI	February 15, 2013	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	1739	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as an additive component to engine lubricants. Based on test data on the PVN substance, as well as SAR analysis of test data on analogous aliphatic amines and esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 2 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 2 ppb may cause significant adverse environmental effects.	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400) and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10963 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	78 FR 28586 (May 15, 2013) https://www.gpo.gov/fdsys/pkg/FR-2013-05-15/pdf/2013-11507.pdf
P-13-908	Polyether polyester urethane phosphate (generic).	Not available	CBI	September 9, 2013	N/A	N/A	December 9, 2014	456	September 21, 2017	N/A	November 20, 2017	1533	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as an additive. Based on SAR analysis of test data on analogous inorganic phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water exceed releases from manufacturing, processing, and use levels described in the PMN. For the manufacturing, processing, and use operations described in the PMN, environmental releases did not exceed 5 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. However, EPA has determined that, if in the future there is domestic manufacture, the use changes from that described in the PMN, or if the production volume increases substantially, the potential for release to the environment may change correspondingly and can result in significant adverse environmental effects.	Recommended testing: EPA has determined that the results of an algal toxicity test (OCSPP Test Guideline 850.4500), with the PVN substance substituted for the phosphate nutrient in the algal growth medium, would help characterize the environmental effects of the PVN substance.	40 CFR 721.10964 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-14-129	Propanamide, 2-hydroxy-N,N-dimethyl-	35123-06-9	CBI	December 3, 2013	N/A	N/A	June 2, 2014	181	September 21, 2017	N/A	November 20, 2017	1448	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as a solvent in pesticide formulations and solvent for fertilizers. Based on test data on the PVN substance, EPA identified concerns for solvent neurotoxicity, blood and liver toxicity, kidney effects, and developmental toxicity. For the uses described in the PVN, EPA does not expect significant dermal or inhalation occupational exposures, nor does it expect consumer exposures. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however that any use of the substance other than as described in the PVN, any use of the PVN substance without the use of dermal protection, where there is a potential for dermal exposures; or any use of the PVN substance in consumer products may cause serious human health effects.	Recommended testing: EPA has determined that the results of a dermal penetration test (OPPTS Test Guideline 870.7600) would help characterize the human health effects of the PVN substance.	40 CFR 721.10965 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-260	1-Propene, 2-bromo-3,3,3-trifluoro-	1514-82-5	American Pacific Corp	January 16, 2014	March 7, 2016	781	August 29, 2016	956	September 21, 2017	563	November 20, 2017	1404	No		N/A	N/A	The PVN states that the PVN substance will be used as a fire extinguishing agent for: Portable extinguishers (onboard aviation and all nonresidential); niche systems (aircraft, normally unoccupied systems, self-contained automatic fire extinguishing systems); and streaming systems for aircraft rescue fire fighting vehicles. Based on test data on the PVN substance, EPA predicts reproductive effects to unprotected workers from repeated inhalation exposures. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that inhalation monitoring data, collected according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in the docket under docket ID number EPA-HQ-OPPT-2016-0331) would help characterize the human health effects of the PVN substance. The Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10966 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-759	Pyrolysis oil product (generic)	Not available	CBI	July 31, 2014	May 4, 2016	643	N/A	N/A	September 21, 2017	565	November 20, 2017	1208	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as an on-site coolant and petroleum feed-stock. Based on SAR analysis of test data on analogous benzene and alkyl benzenes, EPA identified concerns for oncogenicity, neurological effect, and blood toxicity to unprotected workers from repeated inhalation exposures. Further, based on SAR analysis of test data on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the PVN substance in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the results of a developmental neurotoxicity test (OPPTS Test Guideline 870.6300) with a complete blood count and differential for white blood cells; inhalation monitoring data, collected according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in the docket under docket ID number EPA-HQ-OPPT-2016-0331; a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010) and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance. The Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10967 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-15-279	1-Octanamine, 7(or 8)-(aminomethyl)-	1613320-81-2	CBI	February 6, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	1018	No		N/A	N/A	The PVN states that the substance is used as a raw material for highly heat resistant plastic. Based on test data on the PVN substance, as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 123 parts per billion of the PVN substance in surface waters. As described in the PVN, releases of the substance during the use described in the PVN are not expected to result in surface water concentrations that exceed 123 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PVN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 123 ppb may cause significant adverse environmental effects.	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400) and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10968 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-409	Substituted alkanolamine ether (generic)	Not available.	CBI	April 14, 2015	March 3, 2016	323	April 5, 2016	357	September 21, 2017	567	November 20, 2017	950	No		N/A	N/A	The PVN states that the substance will be used as a hydrogen sulfide scavenger. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PVN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified.	40 CFR 721.10969 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 31371 (June 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-02/pdf/2015-13418.pdf
P-15-583	Butanedioic acid, alkyl amine, dimethylbutyl ester (generic)	Not available	CBI	July 8, 2015	February 8, 2016	215	March 3, 2016	239	September 21, 2017	591	November 20, 2017	866	No		N/A	N/A	The PVN states that the substance will be used as an additive to engine motor oil. Based on physical-chemical properties data, EPA predicts that the PVN substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Further, based on test data on the PVN, as well as SAR analysis of analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substance in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to the environment and human health, the substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PVN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400) and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance. The Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10970 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-672	Carbon nanotube (generic)	Not available	CBI	August 5, 2015	January 15, 2016	153	N/A	N/A	September 21, 2017	615	November 20, 2017	838	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the PVN substance will be in filtration media. Based on test data on analogous respirable, poorly soluble particulates and carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that a two-year inhalation bioassay (OPPTS 870.4200); a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize possible health and environmental effects of the substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10971 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 64409 (October 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-27031.pdf
P-15-678	Metal salt of mineral acid, reaction products with aluminia, aluminium hydroxide, aluminum hydroxide oxide (Al(OH)O), silica, titanium oxide (TiO2) and 3-(trimoxysilyl)-1-propanamine (generic)	Not available	CBI	August 10, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	833	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as an industrial paper additive. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity if inhaled based on lung overload. As described in the PMN, inhalation is expected to be minimal for this use. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as identified in the PMN may result in serious health effects. Based on this information, the PMN meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PVN substance.	40 CFR 721.10972 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 64409 (October 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-27031.pdf
P-15-766	Halogenated bisphenol A, polymer with epichlorohydrin, alkenoate (generic)	Not available	Reichhold	September 28, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	784	No		N/A	N/A	The PVNs state that the generic (non-confidential) use of the substances will be as resins for flame retardant polyester. Based on test data on the confidential impurity of the PVN substance, EPA identified concerns for chronic toxicity effects to workers and the general population exposed to the PVN substances. Further, based on the confidential impurity, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the impurity in surface waters. As described in the PVNs, EPA does not expect significant occupational exposures, general population exposures, nor releases of the substance to result in surface water concentrations that exceed 20 ppb of the impurity in surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any consumer use, any use other than as described in the PVNs, or any increase in production volume over 10,000 kg/yr may result in serious human health and significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a combined repeated dose toxicity test (OECD Test Guideline 422) with the reproduction/developmental toxicity screening test; a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substances.	40 CFR 721.10973 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 70201 (November 13, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-11-13/pdf/2015-28842.pdf
P-15-767	Halogenated bisphenol A, polymer with bisphenol A diglycidyl ether and epoxidized phenol-formaldehyde resin, alkenoate (generic)	Not available	Reichhold	September 29, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	783	No		N/A	N/A	The PVNs state that the generic (non-confidential) use of the substances will be as resins for flame retardant polyester. Based on test data on the confidential impurity of the PVN substance, EPA identified concerns for chronic toxicity effects to workers and the general population exposed to the PVN substances. Further, based on the confidential impurity, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the impurity in surface waters. As described in the PVNs, EPA does not expect significant occupational exposures, general population exposures, nor releases of the substance to result in surface water concentrations that exceed 20 ppb of the impurity in surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any consumer use, any use other than as described in the PVNs, or any increase in production volume over 10,000 kg/yr may result in serious human health and significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a combined repeated dose toxicity test (OECD Test Guideline 422) with the reproduction/developmental toxicity screening test; a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substances.	40 CFR 721.10974 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 70201 (November 13, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-11-13/pdf/2015-28842.pdf
P-16-14	Silicon, tris[dialkyl phenyl]-dialkyl-dioxoalkane-naphthalene disulfonate (generic)	Not available	CBI	October 7, 2015	N/A	N/A	March 23, 2016	168	September 21, 2017	N/A	November 20, 2017	775	No		N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as an ink additive. Based on test data on the PVN substance, as well as SAR analysis of test data on analogous diketones, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 6 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance during the use described in the PVN are not expected to result in surface water concentrations that exceed 6 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PVN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 6 ppb may cause significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a ready biodegradability test (OECD Test Guideline 301); a fish early-life state toxicity test (OCSPP Test Guideline 850.1400); and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10975 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 77626 (December 15, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-15/pdf/2015-31522.pdf

P-16-40	Tar acids fraction (generic).	Not available	CBI	October 27, 2015 (Reissued January 4, 2016)	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	753	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as a polymer. Based on test data on the PVN substance, as well as SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 45 ppb of the PVN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PVN are not expected to result in surface water concentrations that exceed 45 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PVN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 45 ppb may cause significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life state toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10976 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	80 FR 77626 (December 15, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-15/pdf/2015-31522.pdf
P-16-59	Dialkyl fattyalkylamino propanamide alkylamine (generic)	Not available	CBI	November 3, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	748	No	N/A	N/A	The PVNs state that the substances will be used as chemical intermediates. Based on data on the PVN substances, as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. As described in the PVNs, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substances meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances.	40 CFR 721.10977 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-60	Fattyalkylaminopropanoate ester (generic)	Not available	CBI	November 3, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	748	No	N/A	N/A	The PVNs state that the substances will be used as chemical intermediates. Based on data on the PVN substances, as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. As described in the PVNs, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substances meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances.	40 CFR 721.10978 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-70	Boron-sodium oxide (B5Na08), labeled with boron-10	200443-98-7	3M Company	November 5, 2015	N/A	N/A	August 22, 2016	291	September 21, 2017	N/A	November 20, 2017	746	No	N/A	N/A	The PVN states that this substance is to be used as an emergency shutdown coolant in boiling water reactors. Based on test data for boron compounds, the EPA identified potential human health concerns regarding reproductive effects, developmental toxicity, neurotoxicity, and blood effects from exposure to the PVN substance via inhalation exposure. Further, based on SAR analysis of test data on boron compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1,240 ppb of the PVN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PVN, exceed releases from the use described in the PVN. For the use described in the PVN, inhalation and dermal exposures are expected to be minimal and environmental releases did not exceed 1,240 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PVN may result in serious human health and significant adverse environmental effects. Based on this information, the PVN substance meet the concern criteria at § 721.170(b)(3)(i) and (b)(4)(i).	Recommended testing: EPA has determined that the results of a reproductive/developmental toxicity screening test (OPPTS 870.3550/OECD Test Guideline 421); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance.	40 CFR 721.10979 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-94	Perfluoropolyether modified organosilane (generic).	Not available	Shin-Etsu Silicones of America	November 13, 2015	N/A	N/A	September 27, 2016	319	September 21, 2017	N/A	November 20, 2017	738	No	N/A	N/A	The PVN states that the substance will be used as a stain-proof coating agent for touch panel. Based on physical-chemical properties data on the PVN substance, as well as SAR analysis of test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. EPA predicts adverse effects to human health and the environment may occur if releases of the PVN substance to surface water at production volumes higher than described in the PVN exceed the releases expected from the production volume described in the PVN. For the described production volume in the PVN, significant environmental releases are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any substantial combined production volume increase could result in exposures which may cause serious human health and significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(1)(i)(D), (b)(3)(iii), and (b)(4)(iv).	Recommended testing: EPA has determined that the results of an indirect photolysis screening test; sunlight photolysis in waters containing dissolved humic substances (OPPTS Test Guideline 835.5270), and simulation tests to assess the primary and ultimate biodegradability of chemicals discharged to wastewater (OPPTS Test Guideline 835.3280/OECD Test Guideline 314) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10980 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-95	Modified phenol-formaldehyde resin (generic).	Not available	CBI	November 16, 2015 (Reissued April 11, 2016)	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	735	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as a flame retardant additive. Based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 96 ppb of the PVN substance in surface waters. Further, based on the alcohol groups, EPA has concerns for irritation to eyes, lungs, and mucous membranes. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 96 ppb and exposures to workers and general population are minimal due to the use as a flame retardant additive. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as stated in the PVN or any use of the substance resulting in surface water concentrations exceeding 96 ppb may result in serious human health and significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of an acute toxicity test (OPPTS Test Guideline 870.1300); a repeated dose 28-day oral toxicity study (OPPTS Test Guideline 870.3050); in rodents; a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395); a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance.	40 CFR 721.10981 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-101	Disubstituted benzene alkanal (generic).	Not available	CBI	November 20, 2015	N/A	N/A	June 9, 2016	202	September 21, 2017	N/A	November 20, 2017	731	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a component for household products, including cleaning, fabric and air care. Based on SAR analysis of test data on analogous structurally similar substances, EPA identified concerns for developmental toxicity from dermal exposures of the PVN substance to workers and consumers. For the use described in the PVN, dermal exposures are not expected based on the use of impervious gloves, and consumer dermal exposures are expected to be minimal. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of PVN substance without the use of dermal protection, where there is a potential for dermal exposures, or any use of the PVN substance other than for the use specified in the PMN may result in serious human health effects. Based on this information, the PVN substance meet the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that results of a 90-day oral toxicity test (OPPTS Test Guideline 870.3100) in rats via the gavage route, and a developmental toxicity test (OPPTS Test Guideline 870.3650) in rats via the gavage route would help characterize the effects of the PVN substance.	40 CFR 721.10982 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-102	Phthalic anhydride, polymer with alkylene glycol and alkanepolyol, acrylate (generic).	Not available	CBI	November 23, 2015 (Reissued May 13, 2016)	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	730	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as a coating component. Based on SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance during the use described in the PVN are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PVN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a water solubility test (OPPTS Test Guideline 830.7840, a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); and algal toxicity test (OCSPP Test Guideline 850.4500); would help characterize the environmental effects of the PVN substance.	40 CFR 721.10983 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-104	2-Pyridinecarboxylic acid, 4,5-dichloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-	1546765-39-2	CBI	November 24, 2015	N/A	N/A	July 25, 2016	244	September 21, 2017	N/A	November 20, 2017	727	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as a feed stock for an intermediate. Based on SAR analysis of test data on analogous halopyridines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb of the PVN substance in surface waters. Further, based on the acid moiety, EPA has concern for irritation to eyes, lungs, and mucous membranes. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 8 ppb and exposures to workers and general population are minimal due to the use as an intermediate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as an intermediate or any use of the substance resulting in surface water concentrations exceeding 8 ppb may result in serious human health and significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of an acute toxicity test (OPPTS Test Guideline 870.1000); a repeated dose 28-day oral toxicity study (OPPTS Test Guideline 870.3050) ; in rodents; a bacterial reverse mutation test (OPPTS Test Guideline 870.5100); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance.	40 CFR 721.10984 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-136	Dialkylamino alkylamide inner salt (generic).	Not available	CBI	December 15, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	706	No	N/A	N/A	The PVNs state that the generic (non-confidential) use of these substances is in oil production. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. As described in the PVNs, releases of these substances are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substances meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a mysid chronic toxicity test (OCSPP Test Guideline 850.1350); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance. Testing should be conducted on PVN substance P-16-139.	40 CFR 721.10985 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 7337 (February 11, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-02-11/pdf/2016-02830.pdf
P-16-139	Dialkylamino alkylamide inner salt (generic).	Not available	CBI	December 15, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	706	No	N/A	N/A	The PVNs state that the generic (non-confidential) use of these substances is in oil production. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. As described in the PVNs, releases of these substances are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substances meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a mysid chronic toxicity test (OCSPP Test Guideline 850.1350); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances. Testing should be conducted on PVN substance P-16-139.	40 CFR 721.10985 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 7337 (February 11, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-02-11/pdf/2016-02830.pdf
P-16-140	Dialkylamino alkylamide inner salt (generic).	Not available	CBI	December 15, 2015	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	706	No	N/A	N/A	The PVNs state that the generic (non-confidential) use of these substances is in oil production. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. As described in the PVNs, releases of these substances are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substances meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a mysid chronic toxicity test (OCSPP Test Guideline 850.1350); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances. Testing should be conducted on PVN substance P-16-139.	40 CFR 721.10985 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 7337 (February 11, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-02-11/pdf/2016-02830.pdf
P-16-170	Nanocarbon (generic)	Not available	CBI	January 8, 2016	June 21, 2016	165	October 3, 2016	269	September 21, 2017	457	November 20, 2017	317	No	N/A	N/A	The PVN states that the substance will be used as an additive to composite materials. Based on test data on analogous respirable, poorly soluble particulates and nanocarbon materials, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other nanocarbon materials EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide a dustiness test (European Standard EU 15051) by six months from commencement of manufacture. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10986 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 14106 (March 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-03-16/pdf/2016-05970.pdf
P-16-177	Barium molybdenum niobium tantalum tellurium vanadium zinc oxide	1440529-21-4	CBI	February 12, 2016	N/A	N/A	February 2, 2017	356	September 21, 2017	N/A	November 20, 2017	282	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as a glass coating. Based on SAR analysis of test data on the analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects to workers exposed to the PVN substance. As described in the PVN, worker exposure will be minimal due to the use of adequate respiratory protection. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without a National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10, where there is potential respiratory exposure, any use other than in the PVN, or domestic manufacture may result in serious human health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a 90-day subchronic toxicity test (OPPTS Test Guideline 870.3465) via the inhalation route with a 60-day holding period would help characterize the human health effects of the PVN substance.	40 CFR 721.10987 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 20633 (April 8, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08135.pdf
P-16-179	Alkanoic acids, esters with alkanetriol (generic).	Not available	CBI	January 14, 2016	N/A	N/A	July 14, 2016	182	September 21, 2017	N/A	November 20, 2017	311	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance is as a agrease. Based on SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10988 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 14106 (March 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-03-16/pdf/2016-05970.pdf

P-16-182	Manganese, tris[.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1, .kappa.N4, .kappa.N7)di- (P-16-182, chemical A); Manganese, [.mu.-(acetato-.kappa.O:.kappa.O')]bis[.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1, .kappa.N4, .kappa.N7)di- (P-16-182, chemical B); Manganese, bis[.mu.-(acetato-.kappa.O:.kappa.O')][.mu.-(2-ethylhexanoato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1, .kappa.N4, .kappa.N7)di- (P-16-182, chemical C); and Manganese, tris[.mu.-(acetato-.kappa.O:.kappa.O')]bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1, .kappa.N4, .kappa.N7)di- (P-16-182, chemical D).	2020407-62-7 (P-16-182, chemical A); 2020407-63-8 (P-16-182, chemical B); 2020407-64-9 (P-16-182, chemical C); 2020407-65-0 (P-16-182, chemical D)	Huntsman International, LLC	January 15, 2016	N/A	N/A	October 15, 2016	274	September 21, 2017	N/A	November 20, 2017	310	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as resins. Based on SAR analysis of test data on analogous compounds, EPA identified concerns for systemic effects to the thyroid and pituitary gland, liver toxicity, developmental and reproductive toxicity, and mutagenicity. There are also concerns for immunotoxicity, reproductive and developmental toxicity, neurotoxicity, blood effects, and kidney toxicity, and uncertain concerns for asthma and oncogenicity, based on manganese, and concerns for developmental toxicity for branched acid hydrolysis products, by analogy to valproic acid and other acids that are branched on the carbon adjacent to the acid group, all based on exposure to the PMN substances via inhalation or dermal exposure. As described in the PMN, exposure is expected to be minimal due to negligible inhalation exposures and use of adequate dermal personal protection equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any domestic manufacturer; any manufacture of the PMN substances at a concentration greater than 10% in any formulation; or any use of the PMN substances without the use of chemical impervious gloves, where there is a potential for dermal exposures may result in serious human health effects. Based on this information, the PMN substances meet the concern criteria at 40 CFR 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a combined repeated dose toxicity reproduction/development toxicity screening test (OECD Test Guideline 422) would help characterize the human health effects of the PMN substances.	40 CFR 721.10989 (P-16-182, chemical A), 40 CFR 721.10990 (P-16-182, chemical B), 40 CFR 721.10991 (P-16-182, chemical C), and 40 CFR 721.10992 (P-16-182, chemical D) 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 14106 (March 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-03-16/pdf/2016-05970.pdf
P-16-190	Aryl polyolefin (generic).	Not available.	CBI	January 19, 2016	N/A	N/A	May 20, 2016	122	September 21, 2017	N/A	November 20, 2017	306	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a lubricant. Based on analogy to C10-13 alkyl derivatives of benzene, EPA identified concerns for reproductive and developmental toxicity to workers exposed to the PMN substance based on exposure to the PMN substance via dermal exposure. As described in the PMN, exposure is expected to be minimal due to use of adequate dermal personal protection equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN, or any use without the use of dermal protection where there is a potential for dermal exposures may cause serious human health effects. Based on this information, the PMN substance meets the concern criteria at 40 CFR 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a two-generation reproduction toxicity test (OECD Test Guideline 416) would help characterize the human health effects of the PMN substance.	40 CFR 721.10993 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 14106 (March 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-03-16/pdf/2016-05970.pdf
P-16-260	Melamine nitrate (generic).	Not available	CBI	March 16, 2016	N/A	N/A	N/A	N/A	September 21, 2017	N/A	November 20, 2017	249	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance is as a gas generant for automobile air bag initiators. Based on test data on the PMN substance, as well as SAR analysis of test data on analogous melamines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water concentrations that exceed 14 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 14 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400) and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10994 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 26224 (May 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-02/pdf/2016-10229.pdf
P-16-272	Lecithins, soya, hydrogenated	308068-11-3	CBI	March 18, 2016	N/A	N/A	September 9, 2016	175	September 21, 2017	N/A	November 20, 2017	247	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance is an ingredient in a formulated product. Based on SAR analysis of test data on analogous amphoteric surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance during the use described in the PMN are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance for the use described in the PMN may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OCSPP Test Guideline 850.1010); an algal toxicity test (OCSPP Test Guideline 850.4500); a fish early-life stage toxicity test (OCSPP Test Guideline 850.1400); and a daphnid chronic toxicity test (OCSPP Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10995 82 FR 44079 (September 21, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-09-21/pdf/2017-20158.pdf	81 FR 26224 (May 2, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-02/pdf/2016-10229.pdf
P-12-292	Coke (coal), secondary pitch	94113-91-4	CBI	April 5, 2012	July 1, 2015	1182	N/A	N/A	November 17, 2016	505	January 17, 2017	1748	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be in the carbon graphite industry. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, subcategory carbon black, EPA identified concerns for lung effects and cancer to workers exposed to the PMN substance by the inhalation route. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of 60 days (including BALF analysis) before exceeding the production volume limits in the consent order. Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information	40 CFR 721.10928 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	77 FR 24705 (April 25, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-04-25/pdf/2012-9919.pdf
P-13-718	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	July 11, 2013	July 1, 2015	720	N/A	N/A	November 17, 2016	505	January 17, 2017	1286	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as: a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929. 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-13-719	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	July 11, 2013	July 1, 2015	720	N/A	N/A	November 17, 2016	505	January 17, 2017	1286	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as: a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929. 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-13-720	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	July 11, 2013 (Reissued June 22, 2016)	July 1, 2015	720	N/A	N/A	November 17, 2016	505	January 17, 2017	1286	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as: a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929. 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-13-721	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	July 11, 2013	July 1, 2015	720	N/A	N/A	November 17, 2016	505	January 17, 2017	1286	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as: a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929. 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-14-655	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	June 30, 2014	July 1, 2015	366	N/A	N/A	November 17, 2016	505	January 17, 2017	932	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as: a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929. 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf

P-14-656	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	June 30, 2014	July 1, 2015	366	N/A	N/A	November 17, 2016	505	January 17, 2017	932	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929. 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-657	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	June 30, 2014	July 1, 2015	366	N/A	N/A	November 17, 2016	505	January 17, 2017	932	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929. 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-658	Single-walled carbon nanotubes (generic).	Claimed confidential.	Nano-C, Inc	June 30, 2014	July 1, 2015	366	N/A	N/A	November 17, 2016	505	January 17, 2017	932	No	N/A	N/A	The PMNs state that the use of the PMN substances will be as a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electro-mechanical switch in electronic circuitry and devices; a film laminate to improve structural, electrical or electro-chemical properties of composite materials; a film laminate to improve conductivity in batteries, capacitors and fuels cells; with composite materials to improve their mechanical properties and electrical conductivities; catalyst support for use in fuel cells; in a nanoporous network in gas diffusion layers; for separation of chemicals; an additive to improve corrosion resistance of metals; an additive in lubricants and greases to improve wear resistance; an additive for transparency and conductivity in electronic devices; an additive for fibers in structural and electrical applications; an additive for fibers in fabrics and as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and other carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other carbon nanotubes, EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the physical/chemical properties data within the specified time limits. In addition, the submitter has agreed not to exceed the confidential production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post-exposure observation period of up to 9 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart). Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10929 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-150	Fatty acid amides (generic).	Claimed confidential.	CBI	December 16, 2013	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1128	No	N/A	N/A	The PMNs states that these substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA expects toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of PMNs P-14-150 and P-14-165, 2 ppb of PMN P-16-166, and 4 ppb of PMNs P-14-151 and P-14-152 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb (P-15-150 and P-14-165), 2 ppb (P-16-166), or 4 ppb (P-15-151 and P-15-152) may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 830.4500) would help characterize the environmental effects of the PMN substances P-14-150, P-14-151, and P-14-152. Further, EPA has determined results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements, as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances P-14-165 and P-14-166. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate solubility in the test media, because of the low water solubility of the PMNs. EPA recommends conducting the water solubility and log Kow measurements testing first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10930 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-151	Fatty acid amides (generic).	Claimed confidential.	CBI	December 16, 2013	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1128	No	N/A	N/A	The PMNs states that these substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA expects toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of PMNs P-14-150 and P-14-165, 2 ppb of PMN P-16-166, and 4 ppb of PMNs P-14-151 and P-14-152 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb (P-15-150 and P-14-165), 2 ppb (P-16-166), or 4 ppb (P-15-151 and P-15-152) may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 830.4500) would help characterize the environmental effects of the PMN substances P-14-150, P-14-151, and P-14-152. Further, EPA has determined results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements, as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances P-14-165 and P-14-166. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate solubility in the test media, because of the low water solubility of the PMNs. EPA recommends conducting the water solubility and log Kow measurements testing first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10930 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-152	Fatty acid amides (generic).	Claimed confidential.	CBI	December 16, 2013	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1128	No	N/A	N/A	The PMNs states that these substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA expects toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of PMNs P-14-150 and P-14-165, 2 ppb of PMN P-16-166, and 4 ppb of PMNs P-14-151 and P-14-152 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb (P-15-150 and P-14-165), 2 ppb (P-16-166), or 4 ppb (P-15-151 and P-15-152) may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 830.4500) would help characterize the environmental effects of the PMN substances P-14-150, P-14-151, and P-14-152. Further, EPA has determined results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements, as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances P-14-165 and P-14-166. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate solubility in the test media, because of the low water solubility of the PMNs. EPA recommends conducting the water solubility and log Kow measurements testing first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10930 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-165	Fatty acid amides (generic).	Claimed confidential.	CBI	December 16, 2013	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1128	No	N/A	N/A	The PMNs states that these substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA expects toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of PMNs P-14-150 and P-14-165, 2 ppb of PMN P-16-166, and 4 ppb of PMNs P-14-151 and P-14-152 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb (P-15-150 and P-14-165), 2 ppb (P-16-166), or 4 ppb (P-15-151 and P-15-152) may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 830.4500) would help characterize the environmental effects of the PMN substances P-14-150, P-14-151, and P-14-152. Further, EPA has determined results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements, as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances P-14-165 and P-14-166. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate solubility in the test media, because of the low water solubility of the PMNs. EPA recommends conducting the water solubility and log Kow measurements testing first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10930 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-166	Fatty acid amides (generic).	Claimed confidential.	CBI	December 16, 2013	N/A	N/A	April 4, 2016 (reissued February 23, 2017)	840	November 17, 2016	N/A	January 17, 2017	1128	No	N/A	N/A	The PMNs states that these substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA expects toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of PMNs P-14-150 and P-14-165, 2 ppb of PMN P-16-166, and 4 ppb of PMNs P-14-151 and P-14-152 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb (P-15-150 and P-14-165), 2 ppb (P-16-166), or 4 ppb (P-15-151 and P-15-152) may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 830.4500) would help characterize the environmental effects of the PMN substances P-14-150, P-14-151, and P-14-152. Further, EPA has determined results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements, as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances P-14-165 and P-14-166. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate solubility in the test media, because of the low water solubility of the PMNs. EPA recommends conducting the water solubility and log Kow measurements testing first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10930 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-413	Kaolin, reaction products with polysiloxane (generic).	Claimed confidential.	CBI	March 12, 2014	October 22, 2015	589	N/A	N/A	November 17, 2016	392	January 17, 2017	1042	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an insulator. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects to workers exposed to the PMN substance by the inhalation route. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: The submitter has agreed to provide a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of 60 days (including BALF analysis) before exceeding the production volume limit in the consent order. Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10931 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf

P-14-428	Fatty acid amides (generic).	Claimed confidential.	CBI	March 19, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1035	No	N/A	N/A	Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concentration values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431, may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10932 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
P-14-429	Fatty acid amides (generic).	Claimed confidential.	CBI	March 19, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1035	No	N/A	N/A	Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concentration values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431, may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10932 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
P-14-430	Fatty acid amides (generic).	Claimed confidential.	CBI	March 19, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1035	No	N/A	N/A	Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concentration values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431, may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10932 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
P-14-431	Fatty acid amides (generic).	Claimed confidential.	CBI	March 19, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	1035	No	N/A	N/A	Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concentration values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb of P-14-428 and P-14-430, and 2 ppb of P-14-429 and P-14-431, may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10932 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
P-14-523	Copolymers of perfluorinated and alkyl methacrylates (generic)	Claimed confidential.	CBI	April 29, 2014	August 24, 2015	482	October 9, 2015	528	November 17, 2016	451	January 17, 2017	994	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as additives for textile finishing. Based on physical-chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a 90-day inhalation toxicity test in rats (OPPTS Test Guideline 870.3465/OECD Test Guideline 413) with a 60-day holding period, and an avian reproduction test (OECD Test Guideline 206) in mallard ducks would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10933 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
P-14-524	Copolymers of perfluorinated and alkyl methacrylates (generic)	Claimed confidential.	CBI	April 29, 2014	August 24, 2015	482	N/A	N/A	November 17, 2016	451	January 17, 2017	994	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as additives for textile finishing. Based on physical-chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a 90-day inhalation toxicity test in rats (OPPTS Test Guideline 870.3465/OECD Test Guideline 413) with a 60-day holding period, and an avian reproduction test (OECD Test Guideline 206) in mallard ducks would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10933 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
P-14-525	Copolymers of perfluorinated and alkyl methacrylates (generic)	Claimed confidential.	CBI	April 29, 2014	August 24, 2015	482	N/A	N/A	November 17, 2016	451	January 17, 2017	994	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as additives for textile finishing. Based on physical-chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a 90-day inhalation toxicity test in rats (OPPTS Test Guideline 870.3465/OECD Test Guideline 413) with a 60-day holding period, and an avian reproduction test (OECD Test Guideline 206) in mallard ducks would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10933 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-526	Copolymers of perfluorinated and alkyl methacrylates (generic).	Claimed confidential.	CBI	April 29, 2014	August 24, 2015	482	N/A	N/A	November 17, 2016	451	January 17, 2017	994	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as additives for textile finishing. Based on physical-chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a 90-day inhalation toxicity test in rats (OPPTS Test Guideline 870.3465/OECD Test Guideline 413) with a 60-day holding period, and an avian reproduction test (OECD Test Guideline 206) in mallard ducks would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10933 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-527	Copolymers of perfluorinated and alkyl methacrylates (generic).	Claimed confidential.	CBI	April 29, 2014	August 24, 2015	482	N/A	N/A	November 17, 2016	451	January 17, 2017	994	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as additives for textile finishing. Based on physical-chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a 90-day inhalation toxicity test in rats (OPPTS Test Guideline 870.3465/OECD Test Guideline 413) with a 60-day holding period, and an avian reproduction test (OECD Test Guideline 206) in mallard ducks would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10933 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-580	Alkenoic acid, polymer with alkyl alkenoate, alkylalkylalkenoate, alkenoic acid and tridecafluoro alkylalkenoate, compds. with alkylaminoalkanol (generic).	Claimed confidential.	CBI	May 30, 2014	October 21, 2015	509	N/A	N/A	November 17, 2016	393	January 17, 2017	963	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a coating additive. Based on physical chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products, EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to the environment and human health, the substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance and its potential degradation products.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential limits specified. In addition, EPA has determined that the results of a hydrolysis as a function of pH and temperature (OPPTS Test Guideline 835.2130); an indirect photolysis screening test (OPPTS Test Guideline 835.5270); a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.5045 or OECD Test Guideline 302A) with analysis of degradation products; a simulation test-aerobic sewage treatment (activated sludge units) OECD Test Guideline OECD 303A); a phototransformation of chemicals in soils surfaces (Draft OECD Test Guideline Jan. 2002); an acute inhalation toxicity test (OPPTS Test Guideline 870.1300); and a fish short-term reproduction test (OPPTS Test Guideline 890.1350) would help characterize potential human health and environmental effects of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10934 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-643	Titanium oxide compound (generic).	Claimed confidential.	CBI	June 24, 2014	July 15, 2015	386	December 16, 2015	540	November 17, 2016	491	January 17, 2017	938	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a physical characteristics modifier for composite articles. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects to workers exposed to the PMN substance by the inhalation route. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health	Recommended testing: The submitter has agreed to provide a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of 60 days (including BALF analysis) before exceeding the production volume limit in the consent order. Although the order does not require a two-year inhalation bioassay (OPPTS Test Guideline 870.4200), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10935 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-688	Fatty acid amide hydrochlorides (generic).	Claimed confidential.	CBI	July 15, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	917	No	N/A	N/A	The PMNs state that the substances will be used as surfactants for use in asphalt emulsions. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691, may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA recommends that testing be conducted on P-14-688.	40 CFR 721.10936 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-14-689	Fatty acid amide hydrochlorides (generic).	Claimed confidential.	CBI	July 15, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	917	No	N/A	N/A	The PMNs state that the substances will be used as surfactants for use in asphalt emulsions. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691, may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA recommends that testing be conducted on P-14-688.	40 CFR 721.10936 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-14-690	Fatty acid amide hydrochlorides (generic).	Claimed confidential.	CBI	July 15, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	917	No	N/A	N/A	The PMNs state that the substances will be used as surfactants for use in asphalt emulsions. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691, may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA recommends that testing be conducted on P-14-688.	40 CFR 721.10936 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-14-691	Fatty acid amide hydrochlorides (generic).	Claimed confidential.	CBI	July 15, 2014	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	917	No	N/A	N/A	The PMNs state that the substances will be used as surfactants for use in asphalt emulsions. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed their respective concern concentration levels. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, resulting in releases to surface waters exceeding 1 ppb for P-14-688, P-14-689, P-14-690, and 2 ppb for P-14-691, may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA recommends that testing be conducted on P-14-688.	40 CFR 721.10936 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf

P-14-712	Plastics, wastes, pyrolyzed, bulk pyrolysate (generic)	Claimed confidential.	CBI	July 21, 2014	July 27, 2015	371	October 19, 2016	821	November 17, 2016	479	January 17, 2017	911	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of P-14-712 is a petroleum blend stock, of P-14-713 and P-14-714 is a fuel blend stock, and of P-14-715 is a component of grease or wax products. Based on the presence of benzene and naphthalene, EPA identified concerns for oncogenicity, immunotoxicity, liver toxicity, and blood toxicity. There is also a concern that polychlorinated dibenzo-p-dioxins and dibenzofurans could be present in the PMN substances. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that quarterly testing of polychlorinated dibenzo-p-dioxin and dibenzofuran levels for P-14-712 will characterize potential health effects of the PMN substances.	40 CFR 721.10937 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-14-713	Plastics, wastes, pyrolyzed, light distillate (generic)	Claimed confidential.	CBI	July 21, 2014	July 27, 2015	371	December 7, 2016	870	November 17, 2016	479	January 17, 2017	911	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of P-14-712 is a petroleum blend stock, of P-14-713 and P-14-714 is a fuel blend stock, and of P-14-715 is a component of grease or wax products. Based on the presence of benzene and naphthalene, EPA identified concerns for oncogenicity, immunotoxicity, liver toxicity, and blood toxicity. There is also a concern that polychlorinated dibenzo-p-dioxins and dibenzofurans could be present in the PMN substances. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that quarterly testing of polychlorinated dibenzo-p-dioxin and dibenzofuran levels for P-14-712 will characterize potential health effects of the PMN substances.	40 CFR 721.10938 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-14-714	Plastics, wastes, pyrolyzed, middle distillate (generic)	Claimed confidential.	CBI	July 21, 2014	July 27, 2015	371	December 7, 2016	870	November 17, 2016	479	January 17, 2017	911	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of P-14-712 is a petroleum blend stock, of P-14-713 and P-14-714 is a fuel blend stock, and of P-14-715 is a component of grease or wax products. Based on the presence of benzene and naphthalene, EPA identified concerns for oncogenicity, immunotoxicity, liver toxicity, and blood toxicity. There is also a concern that polychlorinated dibenzo-p-dioxins and dibenzofurans could be present in the PMN substances. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that quarterly testing of polychlorinated dibenzo-p-dioxin and dibenzofuran levels for P-14-712 will characterize potential health effects of the PMN substances.	40 CFR 721.10939 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-14-715	Plastics, wastes, pyrolyzed, heavy distillate (generic)	Claimed confidential.	CBI	July 21, 2014	July 27, 2015	371	December 7, 2016	870	November 17, 2016	479	January 17, 2017	911	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of P 14-712 is a petroleum blend stock, of P-14-713 and P-14-714 is a fuel blend stock, and of P-14-715 is a component of grease or wax products. Based on the presence of benzene and naphthalene, EPA identified concerns for oncogenicity, immunotoxicity, liver toxicity, and blood toxicity. There is also a concern that polychlorinated dibenzo-p-dioxins and dibenzofurans could be present in the PMN substances. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that quarterly testing of polychlorinated dibenzo-p-dioxin and dibenzofuran levels for P-14-712 will characterize potential health effects of the PMN substances.	40 CFR 721.10940 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-15-28	Carbon silicon oxide	39345-87-4	CBI	October 14, 2014	September 22, 2015	343	March 30, 2016	533	November 17, 2016	422	January 17, 2017	826	No	N/A	N/A	The PMN states that the generic (non-confidential) use of P-15-28 is a colorant for industrial, architecture, plastics, inks and automotive applications. Based on the presence on data on structurally analogous poorly soluble particulates, EPA identified concerns for lung overload. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that the substance may present an unreasonable risk of injury to human health, and that the substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study, with a 60-day holding period (OPPTS Test Guideline 870.3465), would help characterize human health and environmental effects of the PMN substance. The submitter has agreed to conduct this test within two years of submission of the Notice of Commencement of Manufacture (NOC). EPA has also determined that the results of a Chronic Toxicity test (OPPTS Test Guideline 870.4100) via the inhalation route would further help characterize human health effects of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10941 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-54	Carbon nanotubes (generic)	Claimed confidential.	Zeon Chemicals LP	October 21, 2014	August 31, 2015	314	October 28, 2015	372	November 17, 2016	444	January 17, 2017	819	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the PMN substance will be as a chemical intermediate. Based on test data on analogous respirable, poorly soluble particulates and carbon nanotubes, EPA identified concerns for pulmonary toxicity and oncogenicity. Based on test data for other nanocarbon materials EPA identified concerns for environmental toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain physical-chemical properties, as well as certain human health and environmental toxicity testing would help characterize possible effects of the substance. The submitter has agreed to provide the results of certain physical-chemical property testing annually for at least three years after the commencement of manufacture. The submitter has also agreed to provide the results of a 90-day inhalation toxicity study already being conducted. Although the order does not require a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), or an algal toxicity test (OCSPP Test Guideline 850.4500), the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.	40 CFR 721.10942 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-149	Sulfonated alkylbenzene salts (generic).	Claimed confidential.	CBI	December 17, 2014	September 15, 2015	272	N/A	N/A	November 17, 2016	429	January 17, 2017	762	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be for enhanced oil recovery. Based on test data on analogous surfactants, EPA identified concerns for surfactant effects on the lung and irritation to eyes and mucous membranes. Further, based on structural activity relationship (SAR) analysis of test data on analogous anionics surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. The submitter has agreed to complete this testing by the confidential production volume identified in the consent order. In addition, EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); acute inhalation toxicity test (OPPTS Test Guideline 870.1300); acute eye irritation test (OPPTS Test Guideline 870.2400); and acute dermal irritation test (OPPTS Test Guideline OPPTS 870.2500) would help characterize the potential environmental and human health effects of the PMN substance. The Order does not require these tests at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10943 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	80 FR 9262 (February 20, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-02-20/pdf/2015-03460.pdf
P-15-267	Substituted quinoline derivative (generic).	Claimed confidential	CBI	February 2, 2015	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	715	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a pesticide additive. Based on test data on the PMN substance, EPA identified concerns for chronic toxicity including blood, kidney, and spleen toxicity. As described in the PMN, occupational exposures are expected to be minimal due to the use of adequate personal protective equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without use of impervious dermal protection where there is potential for dermal exposures, use of a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, and use other than as a pesticide additive may result in serious health effects.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.	40 CFR 721.10944 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	80 FR 18227 (April 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-470	Algal oil amide (generic).	Claimed confidential.	CBI	May 15, 2015	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	613	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 2 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10945 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	80 FR 37248 (June 30, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-30/pdf/2015-16047.pdf
P-15-485	Bismuth compound (generic)	Claimed confidential	CBI	May 22, 2015	December 21, 2015	213	February 4, 2016	258	November 17, 2016	332	January 17, 2017	606	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an additive for industrial coatings. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substance. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10946 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	80 FR 37248 (June 30, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-30/pdf/2015-16047.pdf
P-15-612	Sulfur thulium ytterbium yttrium oxide	180189-40-6	BrandWatch Technologies	July 15, 2015	December 21, 2015	159	December 23, 2015	161	November 17, 2016	332	January 17, 2017	552	No	N/A	N/A	The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human heath.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10947 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-613	Gadolinium sulfur ytterbium yttrium oxide, erbium- and thulium-doped	1651187-84-6	BrandWatch Technologies	July 15, 2015	December 21, 2015	159	December 23, 2015	161	November 17, 2016	332	January 17, 2017	552	No	N/A	N/A	The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human heath.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10948 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-614	Gadolinium sulfur ytterbium yttrium oxide, erbium- and thulium-doped	1651158-45-5	BrandWatch Technologies	July 15, 2015	December 21, 2015	159	December 23, 2015	161	November 17, 2016	332	January 17, 2017	552	No	N/A	N/A	The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human heath.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10949 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27926.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf

P-15-615	Erbium gadolinium neodymium sulfur ytterbium yttrium oxide	1651152-96-3	BrandWatch Technologies	July 15, 2015	December 21, 2015	159	December 23, 2015	161	November 17, 2016	332	January 17, 2017	552	No	N/A	N/A	The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10950 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-616	Erbium gadolinium sulfur ytterbium yttrium oxide	1622295-07-1	BrandWatch Technologies	July 15, 2015	December 21, 2015	159	December 23, 2015	161	November 17, 2016	332	January 17, 2017	552	No	N/A	N/A	The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10951 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-617	Erbium gadolinium ytterbium oxide	1651152-06-4	BrandWatch Technologies	July 15, 2015	December 21, 2015	159	January 5, 2016	174	November 17, 2016	332	January 17, 2017	552	No	N/A	N/A	The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10952 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-618	Erbium gadolinium sulfur ytterbium oxide	934388-91-7	BrandWatch Technologies	July 15, 2015	December 21, 2015	159	December 23, 2015	161	November 17, 2016	332	January 17, 2017	552	No	N/A	N/A	The PMNs state that the use of the substances will be as additives for brand protection and anti-counterfeiting inks and polymers. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) (e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability) would help to characterize the health effects of the PMN substance. The submitter has agreed to complete this testing by the aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a 2-year inhalation bioassay (OCSPP Test Guideline 870.4200) would help characterize the potential human health effects of the PMN substances. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10953 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-655	2-Ethylhexanoic acid, compound with alkyamino cyclohexane (generic) (P-15-0655, chemical A); and 2-Ethylhexanoic acid, compound with cyclohexylamine (generic) (P-15-0655, chemical B).	Claimed confidential	CBI	July 29, 2015	N/A	N/A	November 30, 2015	124	November 17, 2016	N/A	January 17, 2017	538	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as an epoxy curing agent. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 ppb of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations that exceed 34 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in releases to surface water concentrations exceeding 34 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10954 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-680	Propenoic acid, alkyl ester, polymer with 1,3-cyclohexanedialkylamine, reaction products with oxirane[alkoxyalkyl] (generic).	Claimed confidential	CBI	August 10, 2015	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	526	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an ingredient in liquid paint coating. Based on data on the PMN substance as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of an activated sludge sorption isotherm test (OPPTS Test Guideline 835.1110); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10955 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 64409 (October 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-27031.pdf
P-15-691	Acrylic acid, polymer with polyalkylene polyamine (generic).	Claimed confidential	CBI	August 17, 2015	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	519	No	N/A	N/A	The PMN states that the use of the substance will be as a chemical intermediate. Based on data on the PMN substance and SAR analysis of test data on analogous polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 5 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a Zahn-Wellens/EMPA Test (OPPTS Test Guideline 835.3200); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a fish acute-toxicity test (OPPTS Test Guideline 850.1085) mitigated by humic acid test; and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10956 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 64409 (October 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-27031.pdf
P-16-30	1,2-Cyclohexanedicarboxylic acid, 1-(2-phenylhydralide)	1807977-72-5	HENKEL Corporation	October 14, 2015	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	461	No	N/A	N/A	The PMN states that the substance will be used as a curing agent in anaerobic adhesive and sealant formulations. Based on test data on analogous hydrazines, EPA identified concerns for blood toxicity, neurotoxicity, oncogenicity, and mutagenicity. Hydrazides are expected to be positive in the chromosome aberration test and positive for lung sensitization. Based on the presence of a free acid, irritation to moist tissue (eyes, lungs, and mucous membranes) is expected. As described in the PMN, occupational exposures are expected to be minimal due to the use of adequate personal protective equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without use of impervious gloves and impervious clothing where there is a potential for dermal exposures, may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i)(A) and (b)(3)(i).	Recommended testing: EPA has determined that the results of a 90-day dermal toxicity test (OPPTS Test Guideline 870.3250) and a carcinogenicity test (OPPTS Test Guideline 870.4200) by the expected route of exposure in two species of rodents, would help characterize the human health effects of the PMN substance.	40 CFR 721.10957 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	80 FR 77626 (December 15, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-15/pdf/2015-31522.pdf
P-16-52	2,5-Furandione, dihydro-, polymer with 1,1'-iminobis[2-propanol], benzoate (ester), N-benoyl derivs	592479-38-4	CBI	November 2, 2015	N/A	N/A	March 31, 2016	150	November 17, 2016	N/A	January 17, 2017	442	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as printing ink. Based on SAR analysis of test data on analogous esters and amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 5 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 5 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10958 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-56	Dialkyl fattyalkylamino propanamide alkylamine acetates (generic).	Claimed confidential	CBI	November 2, 2015	N/A	N/A	May 26, 2016	206	November 17, 2016	N/A	January 17, 2017	442	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances is in oil production. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. As described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in releases to surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a mysid chronic toxicity test (OPPTS Test Guideline 850.1350); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10959 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-57	Dialkyl fattyalkylamino propanamide alkylamine acetates (generic).	Claimed confidential	CBI	November 2, 2015	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	442	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances is in oil production. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. As described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in releases to surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a mysid chronic toxicity test (OPPTS Test Guideline 850.1350); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10959 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-16-58	Dialkylaminopropylaminopropanoate ester (generic).	Claimed confidential	CBI	November 3, 2015	N/A	N/A	N/A	N/A	November 17, 2016	N/A	January 17, 2017	441	No	N/A	N/A	The PMN states that the substance will be used as a chemical intermediate. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 14 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 14 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	The PMN states that the substance will be used as a chemical intermediate. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 14 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 14 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	40 CFR 721.10960 81 FR 81250 (November 17, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-11-17/pdf/2016-27326.pdf	81 FR 1415 (January 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-01-12/pdf/2016-00433.pdf
P-15-276	Functionalized carbon nanotubes (generic).	Claimed confidential	CBI	February 5, 2015	N/A	N/A	May 23, 2016	473	October 27, 2016	N/A	N/A (adverse comments received)	N/A	YES	October 27, 2016	No final SNUR yet	The PMN states that the substance will be used as a thin film for electronic device applications. Based on SAR analysis of test data on analogous carbon nanotubes and other respirable poorly soluble particulates, EPA identified potential lung effects and skin penetration and toxicity induction from inhalation and dermal exposure to the PMN substance. Further, EPA predicts toxicity to aquatic organisms via releases of the PMN substance to surface water. Although there is potential for dermal exposure, EPA does not expect significant occupational exposures due to the use of impervious gloves, and because the PMN is used in a liquid and is not spray applied except in a closed system. Further, EPA does not expect environmental releases during the use identified in the PMN submission. Therefore, EPA has not determined that the proposed manufacturing, processing, and/or use of the substance may present an unreasonable risk to human health or the environment. EPA has determined, however, that any use of the substance without the use of impervious gloves, where there is potential for dermal exposure; manufacturing the PMN substance for use other than as a thin film for electronic device applications; manufacturing, processing, or using the PMN substance in a form other than a liquid; use of the PMN substance involving an application method that generates a mist, vapor, or aerosol except in a closed system; or any release of the PMN substance into surface waters or disposal other than by landfill or incineration may cause serious health effects or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); a 90-day inhalation toxicity test (OPPTS 870.3465) with additional testing parameters beyond those noted at CFR 870.3465, for using the 90-day subchronic protocol for nanomaterial assessment; a two-year inhalation bioassay (OPPTS Test Guideline 870.4200); and a surface charge by electrophoresis (for example, using ASTM E2865-12 or NCL Method PCC-2—Measuring the Zeta Potential of Nanoparticles) would help characterize the health and environmental effects of the PMN substance.	40 CFR 721.10902 81 FR 74755 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-25933.pdf	80 FR 18227 (April 3, 2016) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-378	Diisocyanato hexane, homopolymer, alkanoic acid-polyalkylene glycol ether with substituted alkane (3:1) reaction products-blocked (generic).	Claimed confidential	Allnex USA, Inc	April 3, 2015	N/A	N/A	August 31, 2015	150	October 27, 2016	N/A	N/A (adverse comments received)	N/A	YES	October 27, 2016	No final SNUR yet	The PMN states that the substance will be used as a dual cure/UV cure adhesion/barrier coating for wood substrates. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization. Furthermore, the National Institute for Occupational Safety and Health (NIOSH) alert at http://www.cdc.gov/niosh/docs/2006-149/pdfs/2006-149.pdf summarizes four case reports: one death and several incidents of asthma or other respiratory disease following exposure to methylenebis(phenyl isocyanate) (MDI) during spray-on truck bed lining operations. For this PMN substance, a significant new use is any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products. For new isocyanates submitted as PMNs, EPA expects to issue TSCA section 5(e) orders imposing 0.1% limits on total residual isocyanates and greater levels of respiratory protection (at least an APF of 50, or 1000 if used in a process that generates a vapor or particulate), and no consumer use. The Agency would then likely issue a SNUR defining the significant new use as total residual isocyanates exceeding that 0.1% limit and any use in a consumer product. However, as mentioned in Unit VI., below, and in the original May 16, 2016 direct final rule, EPA designated that date as the cutoff date for determining whether the new use is ongoing. Furthermore, a Notice of Commencement of Manufacture or Import was submitted and the chemical substance is now on the TSCA Inventory and is being used with respiratory protection with an APF of less than 50. For these reasons, EPA is not changing the terms of the original direct final SNUR for this PMN substance. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.	40 CFR 721.10913 81 FR 74755 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-25933.pdf	80 FR 31371 (June 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-02/pdf/2015-13418.pdf

P-15-559	Modified diphenylmethane diisocyanate prepolymer with polyol (generic).	Claimed confidential.	CBI	June 29, 2015	N/A	N/A	October 20, 2015	113	October 27, 2016	N/A	N/A (adverse comments received)	N/A	YES	October 27, 2016	No final SNUR yet	The PVN states that the generic (non-confidential) use of the substance will be as a raw material for flexible foam. Based on SAR analysis of analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PVN substance where the average molecular weight is below 7,500 daltons and any molecular weight species is below 1,000 daltons. For the molecular weight distribution described in the PMN, significant occupational exposures are not expected. Therefore, EPA has not determined that the proposed manufacture of the substance may present an unreasonable risk. EPA has determined, however, that any manufacture of the PVN substance with an average molecular weight below 7,500 daltons, and where any molecular weight species is below 1,000 daltons may cause serious health effects. For new isocyanates submitted as PVNs, EPA expects to issue TSCA section 5(e) orders imposing 0.1% limits on total residual isocyanates and greater levels of respiratory protection (at least an APF of 50, or 1000 if used in a process that generates a vapor or particulate), and no consumer use. The Agency would then likely issue a SNUR defining the significant new use as total residual isocyanates exceeding that 0.1% limit and any use in a consumer product. However, as mentioned in Unit VI., below, and in the original May 16, 2016 direct final rule, EPA designated that date as the cutoff date for determining whether the new use is ongoing. Furthermore, a Notice of Commencement of Manufacture or Import was submitted and the chemical substance is now on the TSCA Inventory and is being used with respiratory protection with an APF of less than 50. For these reasons, EPA is not changing the terms of the original direct final SNUR for this PMN substance. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.	40 CFR 721.10920 81 FR 74715 (October 27, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-25933.pdf	80 FR 48855 (August 14, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-08-14/pdf/2015-20018.pdf
P-14-321	Hydrochlorofluoropropane and Hydrochlorofluoropropene (generic).	Claimed confidential.	CBI	February 10, 2014 (Reissued June 22, 2016)	August 12, 2016	914	February 1, 2017	1087	August 24, 2016	12	N/A (No direct final rule issued before proposed rule)	N/A	No	August 24, 2016	No final SNUR yet	The PVN states that the generic (non-confidential) use of the substances will be as site-limited, isolated and recycled intermediates. Based on test data on the PVN substances, EPA identified concerns for acute toxicity including lethality to animals. The Order was issued under TSCA section 5(a)(3)(B)(i)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a subacute inhalation toxicity: 28-day study (OECD Test Guideline 412) in three species: Mouse, rat, and rabbit (6 studies total) and a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD Test Guideline 422) would help characterize the human health effects of the PVN substances. The submitter has agreed to complete this testing by the production limits identified in the consent order.	81 FR 57846 (August 24, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20010.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
P-14-323	Hydrochlorofluoropropane and Hydrochlorofluoropropene (generic).	Claimed confidential.	CBI	February 10, 2014 (Reissued June 22, 2016)	August 12, 2016	914	November 22, 2016	1016	August 24, 2016	12	N/A (No direct final rule issued before proposed rule)	N/A	No	August 24, 2016	No final SNUR yet	The PVN states that the generic (non-confidential) use of the substances will be as site-limited, isolated and recycled intermediates. Based on test data on the PVN substances, EPA identified concerns for acute toxicity including lethality to animals. The Order was issued under TSCA section 5(a)(3)(B)(i)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a subacute inhalation toxicity: 28-day study (OECD Test Guideline 412) in three species: Mouse, rat, and rabbit (6 studies total) and a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD Test Guideline 422) would help characterize the human health effects of the PVN substances. The submitter has agreed to complete this testing by the production limits identified in the consent order.	81 FR 57846 (August 24, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20010.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22039.pdf
Pre-Enactment SNURS																			
P-11-150	Alkali transition metal oxide (generic)	Claimed confidential	CBI	January 4, 2011	April 14, 2015	1561	N/A	N/A	May 16, 2016	398	July 15, 2016	2019	No	N/A	N/A	Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a battery material. Based on test data on the PVN substance and structural activity relationship (SAR) analysis of test data on analogous respirable, poorly soluble particulates, subcategory titanium dioxide, EPA identified concerns for lung, blood, kidney, and adrenal toxicity, neurotoxicity, developmental toxicity, developmental neurotoxicity, cardiovascular and gastrointestinal effects, and immunosuppression. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health.	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and various parameters of the bronchoalveolar lavage fluid (BALF) e.g., maker enzyme activities, total protein content, total cell count, cell differential, and cell viability. It is not necessary to look at internal organs. EPA recommends that a recovery period of 60 days be included to assess the progression or regression of any lesions would help characterize possible health effects of the substance. The submitter has agreed to complete this testing by the confidential aggregate production volume identified in the consent order. In addition, EPA has determined that the results of a carcinogenicity test (OPPTS Test Guideline 870.4200) would help characterize the potential human health effects of the PVN substance. The Order does not require this test at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10875 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	76 FR 32188 (June 3, 2011) https://www.gpo.gov/fdsys/pkg/FR-2011-06-03/pdf/2011-13672.pdf
P-11-484	Perfluoroalkyl substituted alkyl sulfonate (generic)	Claimed confidential	CBI	July 8, 2011	October 30, 2014	1210	N/A	N/A	May 16, 2016	564	July 15, 2016	1834	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as surfactants. Based on physical chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products including perfluorooctanoic acid (PFOA), perfluorooctanesulfonate (PFOS), perfluorohexane sulfonate (PFHS), and 1H,1H,2H,2H-perfluorooctanesulfonic acid (6-2 FTSA), EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Further, based on test data on P-11-484, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2,800 and 1 part per billion (ppb) respectively for PMN substances P-11-484 and P-11-543 respectively in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain environmental fate and human health and environmental toxicity testing would help characterize human health and environmental effects of the PMN substances. The submitter has agreed to conduct the testing identified in the consent agreement by the confidential triggers identified in the consent order. Further, EPA has determined that the results of an acute inhalation toxicity test (OPPTS Test Guideline 870.1300) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with a post-exposure observation period of up to 3 months and BALF analysis would help characterize the human health effects from spray application of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10876 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	76 FR 58498 (September 21, 2011) https://www.gpo.gov/fdsys/pkg/FR-2011-09-21/pdf/2011-23973.pdf
P-11-543	Polyfluorinated alkyl quaternary ammonium chloride (generic)	Claimed confidential	CBI	July 26, 2011	October 30, 2014	1192	December 1, 2015	1589	May 16, 2016	564	July 15, 2016	1816	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as surfactants. Based on physical chemical properties data, as well as test data on analogous perfluorinated chemicals and potential perfluorinated degradation products including perfluorooctanoic acid (PFOA), perfluorooctanesulfonate (PFOS), perfluorohexane sulfonate (PFHS), and 1H,1H,2H,2H-perfluorooctanesulfonic acid (6-2 FTSA), EPA identified concerns for irritation to skin, eyes, lungs, mucous membranes, lung toxicity, liver toxicity, blood toxicity, male reproductive toxicity, immunosupression, and oncogenicity. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Further, based on test data on P-11-484, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2,800 and 1 part per billion (ppb) respectively for PMN substances P-11-484 and P-11-543 respectively in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain environmental fate and human health and environmental toxicity testing would help characterize human health and environmental effects of the PMN substances. The submitter has agreed to conduct the testing identified in the consent agreement by the confidential triggers identified in the consent order. Further, EPA has determined that the results of an acute inhalation toxicity test (OPPTS Test Guideline 870.1300) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with a post-exposure observation period of up to 3 months and BALF analysis would help characterize the human health effects from spray application of the PMN substances. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10877 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	76 FR 58498 (September 21, 2011) https://www.gpo.gov/fdsys/pkg/FR-2011-09-21/pdf/2011-23973.pdf
P-14-67	Polyfluorinated alkylsulfonyl substituted alkane derivative (generic).	Claimed confidential.	3M Company	November 6, 2013	November 4, 2015	728	N/A	N/A	May 16, 2016	194	July 15, 2016	982	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a polymer additive. EPA has concerns for potential incineration or other decomposition products of the PVN substance. These fluorinated decomposition products may be released to the environment from incomplete incineration of the PVN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers which suggest that under some conditions, the PVN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including PFOA and other perfluorinated alkyls, including the presumed environmental degradant. EPA also has concerns that under some conditions of use, particularly non-industrial, commercial, or consumer use, the PVN substance could cause lung effects, based on limited data on some perfluorinated compounds. Concerns for the PVN substance are for lung toxicity from waterproofing of lung membrane, based on PVN properties. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(II), based on a finding that these substances and their potential degradation products may present an unreasonable risk of injury to the environment and human health.	The PVN states that the generic (non-confidential) use of the substance will be as a polymer additive. EPA has concerns for potential incineration or other decomposition products of the PVN substance. These fluorinated decomposition products may be released to the environment from incomplete incineration of the PVN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers which suggest that under some conditions, the PVN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Further, based on test data on P-11-484, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2,800 and 1 part per billion (ppb) respectively for PMN substances P-11-484 and P-11-543 respectively in surface waters. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. Concerns for the PMN substance are for lung toxicity from waterproofing of lung membrane, based on PMN properties. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(II), based on a finding that these substances and their potential degradation products may present an unreasonable risk of injury to the environment and human health.	Recommended testing: EPA has determined that the results of the modified aerobic activated sludge biodegradation test submitted by the company for EPA review would help characterize the possible degradation of the PMN substance. The submitter has agreed to submit the results of this test by the confidential production volume identified in the consent order. EPA had determined that the results of a phototransformation of chemicals on soil surfaces (Organisation for Economic Co-operation and Development (OECD) Draft Document January 2000) would help characterize the degradation potential of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10878 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-125	1-Octadecanaminium, N-(3-chloro-2-hydroxypropyl)-N,N-dimethyl-, chloride (1:1).	3001-63-6	Colonial Chemical, Inc	December 2, 2013	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	956	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a chemical intermediate for surfactant production. Based on test data on the PVN substance, as well as SAR analysis of test data on analogous cationic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 2 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use resulting in surface water concentrations exceeding 2 ppb may result in significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10879 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-153	Fatty acid rxn products with aminoalkylamines (generic).	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	942	No	N/A	N/A	The PVN states that these substances will be used as chemical intermediates, additives for flotation products, and as adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. For the uses described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, result in releases to surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500); log Kow and water solubility measurements; as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility in the test media. Testing should be tiered, starting with water solubility and log Kow measurements before proceeding with higher tier toxicity tests.	40 CFR 721.10880 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-154	Fatty acid rxn products with aminoalkylamines (generic).	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	942	No	N/A	N/A	The PVN states that these substances will be used as chemical intermediates, additives for flotation products, and as adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. For the uses described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, result in releases to surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500); log Kow and water solubility measurements; as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility in the test media. Testing should be tiered, starting with water solubility and log Kow measurements before proceeding with higher tier toxicity tests.	40 CFR 721.10880 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-15-79	Fatty acid rxn products with aminoalkylamines (generic).	Claimed confidential	CBI	November 6, 2014	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	617	No	N/A	N/A	The PVN states that these substances will be used as chemical intermediates, additives for flotation products, and as adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. For the uses described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, result in releases to surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500); log Kow and water solubility measurements; as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility in the test media. Testing should be tiered, starting with water solubility and log Kow measurements before proceeding with higher tier toxicity tests.	40 CFR 721.10880 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf
P-15-80	Fatty acid rxn products with aminoalkylamines (generic).	Claimed confidential	CBI	November 6, 2014	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	617	No	N/A	N/A	The PVN states that these substances will be used as chemical intermediates, additives for flotation products, and as adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters. For the uses described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding the uses described in the PMNs, result in releases to surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500); log Kow and water solubility measurements; as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility in the test media. Testing should be tiered, starting with water solubility and log Kow measurements before proceeding with higher tier toxicity tests.	40 CFR 721.10880 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf

P-14-155	Fatty acid amides (generic)	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	942	No	N/A	N/A	The PMNs state that the substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 and 3 ppb respectively of the PMN substances P-14-155 and P-14-156 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed 2 ppb and 3 ppb of the PMN substances respectively. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding uses described in the PMNs, resulting in surface water concentrations exceeding 2 ppb (P-14-155) or 3 ppb (P-14-156) of the PMN substances may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements; as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility in the test media, because of the PMN's low water solubility. Testing should be tiered, starting with water solubility and log Kow measurements before proceeding with higher tier toxicity tests.	40 CFR 721.10881 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-156	Fatty acid amides (generic)	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	942	No	N/A	N/A	The PMNs state that the substances will be used as chemical intermediates, additives for flotation products, and adhesion promoters for use in asphalt applications. Based on SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 and 3 ppb respectively of the PMN substances P-14-155 and P-14-156 in surface waters. For the uses described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed 2 ppb and 3 ppb of the PMN substances respectively. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances, excluding uses described in the PMNs, resulting in surface water concentrations exceeding 2 ppb (P-14-155) or 3 ppb (P-14-156) of the PMN substances may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); log Kow and water solubility measurements; as well as either the fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) or the whole sediment acute toxicity invertebrates, freshwater test (OPPTS Test Guideline 850.1735) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility in the test media, because of the PMN's low water solubility. Testing should be tiered, starting with water solubility and log Kow measurements before proceeding with higher tier toxicity tests.	40 CFR 721.10881 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-198	Trialkylammonium borodibenzoate (generic).	Claimed confidential	CBI	December 19, 2013	N/A	N/A	June 16, 2015	544	May 16, 2016	N/A	July 15, 2016	939	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a color developer for general printing applications. Based on test data on the PMN substance and SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 47 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from domestic manufacture or from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 47 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing (defined by statute to include import), processing or use of the substance may present an unreasonable risk. EPA has determined, however, that any domestic manufacture or use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10882 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-324	Fatty ester derivatives, reaction products with alkanolamine, hydroxylated, borated (generic).	Claimed confidential.	CBI	February 10, 2014	N/A	N/A	February 17, 2016	737	May 16, 2016	N/A	July 15, 2016	886	No	N/A	N/A	The PMN states that the substance will be used as a lubricating oil additive. Based on SAR analysis of test data on analogous boron compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 2 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing (defined by statute to include import), processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as a lubricating oil additive may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a chronic fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10883 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22699.pdf
P-14-397	Benzene propanoi, 1-benzoate	60045-26-3	CBI	March 6, 2014	N/A	N/A	August 17, 2015	529	May 16, 2016	N/A	July 15, 2016	862	No	N/A	N/A	The PMN states that the substance will be used as a plasticizer in adhesives for food-product packaging, a diluents-type plasticizer in plastisols, a coalescent in architectural paints and coatings, and a fragrance carrier in fragrances. Based on SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the uses described in the PMN, environmental releases did not exceed 5 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10884 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22699.pdf
P-14-448	Alcohols, C 12-22, distn. Residues	1476777-83-9	Sasol North America Inc	March 25, 2014	N/A	N/A	September 4, 2014	163	May 16, 2016	N/A	July 15, 2016	843	No	N/A	N/A	The PMN states that the use of the substance will be used in formulation of defoamers used in the production of paper. Based on structure-activity relationship SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 7 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface waters exceed releases from the use described in the PMN. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 7 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, any use where the cumulative molecular weights of the C 12 and C 14 components exceed 2 percent by weight of the overall molecular weight of the PMN substance may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. Before conducting these aquatic toxicity testing, EPA recommends chemical characterization of the alkyl range for the alcohol moiety and a water solubility test (OECD Test Guideline 105) should be conducted.	40 CFR 721.10885 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 55450 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22699.pdf
P-14-501	Phosphoric acid, mixed Bu and decyl and octyl and 2-(2-phenoxyethoxy)ethyl and 2-phenoxyethyl esters	1502809-48-4	Ethox Chemicals, LLC	April 21, 2014	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	816	No	N/A	N/A	The PMN states that substances will be used as gellants for use in oil fracturing. Based on structure-activity relationship (SAR) analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PMN substances in surface waters. As described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed 4 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of substances resulting in releases to surface water concentrations exceed ng 4 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10886 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-14-502	Phosphoric acid, mixed Bu and decyl and octyl and 2-(2-phenoxyethoxy)ethyl and 2-phenoxyethyl esters, potassium salts	1502809-56-4	Ethox Chemicals, LLC	April 21, 2014	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	816	No	N/A	N/A	The PMN states that substances will be used as gellants for use in oil fracturing. Based on structure-activity relationship (SAR) analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PMN substances in surface waters. As described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed 4 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of substances resulting in releases to surface water concentrations exceed ng 4 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.	40 CFR 721.10887 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf
P-15-59	Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, reaction products with cadmium zinc selenide sulfide, lauric acid and oleylamine	1623456-01-2	Otis Institute, Inc	October 22, 2014	May 5, 2015	195	May 29, 2015	219	May 16, 2016	377	July 15, 2016	632	No	N/A	N/A	The PMNs state that the substances will be used as a down converter for an optical filter for light emitting diodes used in displays (P-15-59) and as chemical intermediates (P-15-60 and P-15-104). Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and the presence of cadmium, EPA identified concerns for lung effects, kidney effects, and oncogenicity. In addition, EPA predicts chronic toxicity to aquatic organisms from exposure to cadmium. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain material characterization data specified in the consent order on PMN substance P-15-59 would help characterize the possible effects of the PMN substance. The submitter has agreed to submit the results of these studies prior to 3 and 18 month time triggers identified in the consent order. In addition, EPA determined that the results of a metabolism and pharmacokinetics test (OPPTS Test Guideline 870.7485) would help characterize the human health and environmental effect of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10888 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-60	Dodecanoic acid, reaction products with cadmium zinc selenide sulfide and oleylamine	1773514-92-3	Otis Institute, Inc	October 22, 2014	May 5, 2015	195	May 29, 2015	219	May 16, 2016	377	July 15, 2016	632	No	N/A	N/A	The PMNs state that the substances will be used as a down converter for an optical filter for light emitting diodes used in displays (P-15-59) and as chemical intermediates (P-15-60 and P-15-104). Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and the presence of cadmium, EPA identified concerns for lung effects, kidney effects, and oncogenicity. In addition, EPA predicts chronic toxicity to aquatic organisms from exposure to cadmium. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain material characterization data specified in the consent order on PMN substance P-15-59 would help characterize the possible effects of the PMN substance. The submitter has agreed to submit the results of these studies prior to 3 and 18 month time triggers identified in the consent order. In addition, EPA determined that the results of a metabolism and pharmacokinetics test (OPPTS Test Guideline 870.7485) would help characterize the human health and environmental effect of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10889 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-104	Phosphonic acid, P-tetradecyl-, reaction products with cadmium selenide (CdSe)	1773514-66-1	Otis Institute, Inc	November 21, 2014	May 5, 2015	165	May 29, 2015	189	May 16, 2016	377	July 15, 2016	602	No	N/A	N/A	The PMNs state that the substances will be used as a down converter for an optical filter for light emitting diodes used in displays (P-15-59) and as chemical intermediates (P-15-60 and P-15-104). Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and the presence of cadmium, EPA identified concerns for lung effects, kidney effects, and oncogenicity. In addition, EPA predicts chronic toxicity to aquatic organisms from exposure to cadmium. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the development of data on certain material characterization data specified in the consent order on PMN substance P-15-59 would help characterize the possible effects of the PMN substance. The submitter has agreed to submit the results of these studies prior to 3 and 18 month time triggers identified in the consent order. In addition, EPA determined that the results of a metabolism and pharmacokinetics test (OPPTS Test Guideline 870.7485) would help characterize the human health and environmental effect of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10890 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf
P-15-81	Alkyl silicate, polymer with 2-(chloromethyl)oxirane and 4,4'0-(1-methylethylidene)bis[phenol], alkoxylated (generic).	Claimed confidential	CBI	November 7, 2014	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	616	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an ingredient in liquid paint coating. Based on SAR analysis of test data on analogous epoxides, there were health concerns regarding skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive, liver, and kidney toxicity based on the epoxide oxidation product as well as irritations and lung toxicity expected from the ethoxy silane hydrolysis product from exposure to the PMN substance via dermal exposure. Further, based on SAR analysis of test data on analogous epoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, occupational exposures are expected to be minimal due to use of adequate dermal personal protection equipment and releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use without the use of impervious gloves, where there is a potential for dermal exposure, or any use of the substance resulting in surface water concentrations exceeding 1 ppb may result in serious human health or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(1)(i)(C), (b)(3)(i)(I) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD Test Guideline 422); a Zahn-Wellens/EMPA test (OPPTS Test Guideline 835.3200); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.	40 CFR 721.10891 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf
P-15-109	Reaction product of a mixture of aromatic dianhydrides and aliphatic esters with an aromatic diamine (generic).	Claimed confidential.	CBI	November 24, 2014	N/A	N/A	September 22, 2016	668	May 16, 2016	N/A	July 15, 2016	599	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance is as an intermediate. Based on SAR analysis of test data on analogous anilines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 11 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 11 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 11 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); and a ready biodegradability test (OECD Test Guideline 301) would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10892 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf
P-15-111	Fatty acids, tall-oil, reaction products with an ether and triethylenetetramine (generic).	Claimed confidential	Huntsman	November 24, 2014	N/A	N/A	August 7, 2015	256	May 16, 2016	N/A	July 15, 2016	599	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a hardener for coating systems. Based on SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 1 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing (defined by statute to include import), processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any domestic manufacture of the substance, or any use of the PMN substance other than as described in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); and a ready biodegradability test (OECD Test Guideline 301) would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10893 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf
P-15-120	Substituted benzyl acrylate (generic).	Claimed confidential	Miwon North America, INC	November 28, 2014	N/A	N/A	May 11, 2016	530	May 16, 2016	N/A	July 15, 2016	593	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a resin for industrial coating. Based on SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding ng 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); and a ready biodegradability test (OECD Test Guideline 301) would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10894 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf

P-15-154	Fluoroalkyl acrylate copolymer (generic).	Claimed confidential.	CBI	December 18, 2014	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	575	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a textile treatment. The Order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that the substance may present an unreasonable risk of injury to human health and the environment.	Recommended testing: EPA has determined that the results of certain toxicity and environmental fate testing would help characterize the PMN substance. The submitter has agreed to complete the testing identified in the testing section of the consent order by the confidential timlis specified. In addition, EPA has determined that the results of a 90-day inhalation toxicity test in rats (OPPTS Test Guideline 870.3465/OECD Test Guideline 413) with a 60-day holding period, and certain physical chemical property and environmental fate testing identified in the consent order would help characterize the human health and fate effects of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10895 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 9262 (February 20, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-02-20/pdf/2015-03460.pdf
P-15-176	1-Hexanol, 6-mercapto-	1633-78-9	Henkel Corporation	January 9, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	553	No	N/A	N/A	The PMN states that the substance will be used as a chemical intermediate to curable monomers. Based on SAR analysis of test data on analogous thiols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 8 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in surface water concentrations exceeding 8 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); an algal toxicity test (OCSPP Test Guideline 850.4500); and a ready biodegradability test (OECD Test Guideline 301B) would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10896 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-06223.pdf
P-15-177	Phenol, 2,2'-[1,2-disubstituted-1,2-ethanediyl]bis[iminomethylene]bis [substituted- (generic)	Claimed confidential	CBI	January 8, 2015	N/A	N/A	December 16, 2015	342	May 16, 2016	N/A	July 15, 2016	554	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a catalyst in the process to manufacture a crop protection chemical. Based on test data on the PMN substance, EPA identified concerns for blood toxicity to workers from dermal exposures to the PMN substance. As described in the PMN, occupational exposures are expected to be minimal due to use of adequate dermal personal protection equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without the use of chemical impervious gloves, where there is a potential for dermal exposure, or any use of the substance other than as described in the PMN may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a skin absorption, In vitro method (OECD Test Guideline 428) would help characterize the human health effects of the PMN substance.	40 CFR 721.10897 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-06223.pdf
P-15-188	Carbomonoxycies, polymer with substituted heteromonoxycie, succinate, methyl acrylate (generic).	Claimed confidential	Alnex USA Inc	January 16, 2015	N/A	N/A	May 8, 2015	112	May 16, 2016	N/A	July 15, 2016	546	No	N/A	N/A	The PMN states that the substance will be used as a pigment-wetting resin for Ultra Violet (UV)-curable coatings. Based on SAR analysis of test data on analogous methacrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 7 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 7 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a water solubility test (OECD Test Guideline 105); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. The water solubility testing should be conducted prior to conducting the ecotoxicity testing as the results of the water solubility may change the recommended ecotoxicity testing.	40 CFR 721.10898 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-190	Halogenated alkyl trimethylaminium halide (generic).	Claimed confidential	Industrial Speciality Chemicals	January 19, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	543	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be for cationization of starch. Based on test data on analogous alkylating agents, there were health concerns regarding mutagenicity, oncogenicity, developmental toxicity and respiratory sensitization based from exposure to the PMN substance via inhalation exposure. In addition, based on SAR analysis of test data on analogous cationic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 88 ppb of the PMN substance in surface waters. As described in the PMN, exposure is expected to be minimal due to use of adequate respiratory personal protection equipment and releases of the substance are not expected to result in surface water concentrations that exceed 88 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use without the use of NIOSH-certified respirator with an APF of at least 10, where there is a potential for respiratory exposure, or any use of the substance resulting in surface water concentrations exceeding 88 ppb may result in serious human health or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(1)(i)(C), (b)(3)(i) and (b)(4)(i).	Recommended testing: EPA has determined that the results of a bacterial reverse mutation test, (OPPTS Test Guideline 870.5300); a mammalian erythrocyte micronucleus test (OPPTS Test Guideline 870.5395); an acute oral toxicity test (OPPTS Test Guideline 870.1100); a repeated dose 28-day oral toxicity study in rodents (OPPTS Test Guideline 870.3050); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.	40 CFR 721.10899 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-252	Titanium salt, reaction products with silica (generic)	Claimed confidential	CBI	January 30, 2015	N/A	N/A	June 29, 2015	150	May 16, 2016	N/A	July 15, 2016	532	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on analogous insoluble metal oxides, EPA identified concerns for lung toxicity if inhaled based on lung overload for respirable, poorly soluble particulates. For the use described in the PMN, inhalation exposures are expected to be minimal as the PMN is handled in an enclosed process. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use in a non-enclosed process, or any use of the substance other than listed in the PMN may result in significant adverse human health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with 60-day holding period and a particle size distribution/fiber length and diameter distributions (OECD Test Guideline 110) would help characterize the human health effects of the PMN substance.	40 CFR 721.10900 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-272	Formaldehyde, reaction products with aniline and aromatic mono- and di-phenol mixture (generic)	Claimed confidential	Huntsman	February 3, 2015	N/A	N/A	November 19, 2015	289	May 16, 2016	N/A	July 15, 2016	528	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a resin. Based on SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnoids (OPPTS Test Guideline 850.1010); an algal toxicity test (OCSPP Test Guideline 850.4500); and a ready biodegradability (OECD Test Guideline 301) would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10901 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-276	Functionalized carbon nanotubes (generic).	Claimed confidential	CBI	February 5, 2015	N/A	N/A	May 23, 2016	473	May 16, 2016	N/A	July 15, 2016	526	No	N/A	N/A	The PMN states that the substance will be used as a thin film for electronic device applications. Based on SAR analysis of test data on analogous carbon nanotubes and other respirable poorly soluble particulates, EPA identified potential lung effects and skin penetration and toxicity induction from inhalation and dermal exposure to the PMN substance. Further, EPA predicts toxicity to aquatic organisms via releases of the PMN substance to surface water. Although there is potential for dermal exposure, EPA does not expect significant occupational exposures due to the use of impervious gloves, and because the PMN is used in a liquid and is not spray applied except in a closed system. Further, EPA does not expect environmental releases during the use identified in the PMN submission. Therefore, EPA has not determined that the proposed manufacturing, processing, and or use of the substance may present an unreasonable risk to human health or the environment. EPA has determined, however, that any use of the substance without the use of impervious gloves, where there is potential for dermal exposure; manufacturing, processing, or using the PMN substance in a form other than as a liquid; use of the PMN substance involving an application method that generates a mist, vapor, or aerosol; any release of the PMN substance into surface waters; or disposal other than by landfill or incineration may cause serious health effects or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); a 90-day inhalation toxicity test (OPPTS 870.3465) with additional testing parameters beyond those noted at CFR 870.3465, for using the 90-day subchronic protocol for nanomaterial assessment; a two-year inhalation bioassay (OPPTS Test Guideline 870.4200); and a surface charge by electrophoresis (for example, using ASTM E2865-12 or NCL Method PCC-2—Measuring the Zeta Potential of Nanoparticles) would help characterize the health and environmental effects of the PMN substance.	40 CFR 721.10902 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-295	Acrylated mixed metal oxides (generic).	Claimed confidential.	CBI	February 19, 2015	N/A	N/A	February 15, 2016	361	May 16, 2016	N/A	July 15, 2016	512	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an intermediate. Based on SAR analysis of test data on respirable poorly soluble particulates, EPA identified potential lung effects and dermal toxicity from inhalation and dermal exposure to the PMN substance. Further, EPA predicts toxicity to aquatic organisms via releases of the PMN substance to surface water. Although there is potential for dermal exposure, EPA does not expect significant occupational exposures due to the use of impervious gloves, and because the PMN is used in a liquid and is not spray applied. Further, EPA does not expect environmental releases during the use identified in the PMN submission. Therefore, EPA has not determined that the proposed manufacturing, processing, and or use of the substance may present an unreasonable risk to human health or the environment. EPA has determined, however, that any use of the substance without the use of impervious gloves, where there is potential for dermal exposure; manufacturing, processing, or using the PMN substance in a form other than as a liquid; use of the PMN substance involving an application method that generates a mist, vapor, or aerosol; any release of the PMN substance into surface waters; or disposal other than by landfill or incineration may cause serious health effects or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with a 60-day holding period; a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental and health effects of the PMN substance.	40 CFR 721.10903 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-306	Phenol, 1,1-dimethylallyl derivatives (generic).	Claimed confidential	CBI	February 20, 2015	N/A	N/A	November 2, 2015	255	May 16, 2016	N/A	July 15, 2016	511	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a process intermediate. Based on SAR analysis of test data on analogous phenols, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 13 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 13 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 13 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); an algal toxicity test (OCSPP Test Guideline 850.4500); and a Zahn-Wellens/EMPA test (OPPTS Test Guideline 835.3200) would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10904 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-319	Butanedioic acid, 2-methylene-, dialkyl ester (generic).	Claimed confidential.	CBI	February 26, 2015	N/A	N/A	November 19, 2015	266	May 16, 2016	N/A	July 15, 2016	505	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an intermediate for production of a lubricant additive. Based on SAR analysis of test data on analogous acrylates and esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that resulting in surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); an algal toxicity test (OCSPP Test Guideline 850.4500); and a ready biodegradability (OECD Test Guideline 301) would help characterize the environmental effects of the PMN substance. EPA recommends that the fate testing be performed first as the results may mitigate the need for further toxicity testing or change the testing recommendations.	40 CFR 721.10905 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-15-324	Magnesium alkaryl sulfonate (generic).	Claimed confidential.	CBI	March 2, 2015	N/A	N/A	November 19, 2015	262	May 16, 2016	N/A	July 15, 2016	501	No	N/A	N/A	The PMN states that the use of the substance will be as a detergent additive in crankcase lubricant applications. Based on submitted test data on the PMN substance, EPA identified concerns for neurotoxicity and uncertain concerns for cardiac sensitization. Further, based on SAR analysis of test data on analogous substances, EPA identified concerns for developmental toxicity. As described in the PMN, EPA does not expect significant occupational exposures due to use of adequate personal protective equipment, and consumer exposures are not expected as the PMN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN or any use in a consumer product may result in significant adverse human health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(i) and (b)(3)(ii).	Recommended testing: EPA has determined that the results of a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10906 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 22512 (April 22, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-22/pdf/2015-09204.pdf
P-15-326	Polyfluorohydrocarbon (generic).	Claimed confidential.	CBI	March 2, 2015	N/A	N/A	December 21, 2015	294	May 16, 2016	N/A	July 15, 2016	501	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a specialty gas and transfer fluid. Based on test data on the PMN substance, EPA identified concerns for neurotoxicity and uncertain concerns for cardiac sensitization. Further, based on SAR analysis of test data on analogous substances, EPA identified concerns for developmental toxicity. As described in the PMN, EPA does not expect significant occupational exposures due to use of adequate personal protective equipment, and consumer exposures are not expected as the PMN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN or any use in a consumer product may result in significant adverse human health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(i) and (b)(3)(ii).	Recommended testing: EPA has determined that the results of 90-day inhalation toxicity (OPPTS Test Guideline 870.3465) would help characterize the health effects of the PMN substance.	40 CFR 721.10907 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 22512 (April 22, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-22/pdf/2015-09204.pdf
P-15-328	Aluminum calcium oxide salt (generic).	Claimed confidential.	CBI	March 3, 2015	June 2, 2015	91	July 17, 2015	136	May 16, 2016	349	July 15, 2016	500	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the PMN substance will be as a cement additive. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity based on lung overload. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the substance may present an unreasonable risk of injury to human health	Recommended testing: EPA has determined that a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats would help characterize possible health effects of the substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10908 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 22512 (April 22, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-22/pdf/2015-09204.pdf
P-15-332	Polyalkyltrisiloxane (generic).	Claimed confidential	CBI	March 4, 2015	N/A	N/A	July 10, 2015	128	May 16, 2016	N/A	July 15, 2016	499	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a site-limited intermediate. Based on SAR analysis of test data on an analogous substance, there were health concerns regarding liver and kidney toxicity, thyroid effects, and reproductive and developmental toxicity from dermal and inhalation exposures to the PMN substance. Further, based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PMN substance in surface waters. EPA also predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. Further, as described in the PMN, exposure is expected to be minimal due to use of adequate respiratory and dermal personal protection equipment and releases of the substance are not expected to result in surface water concentrations exceeding 4 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface waters exceeding 4 ppb, any use other than that as a site-limited intermediate, or any use without the use of a NIOSH-certified respirator with gas/vapor cartridges and an APF of at least 10 and impervious gloves, may result in serious human health or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a sediment-water lumbricus toxicity test (OECD Test Guideline 225); a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD Test Guideline 422); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance. All ecotoxicity tests should analyze the PMN substance as well as the hydrolysis products.	40 CFR 721.10909 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 22512 (April 22, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-22/pdf/2015-09204.pdf
P-15-356	Oxirane, 2,2'-[[1-[4-[1-methyl-1-[4-(2-oxiranylmethoxy)phenyl]ethyl]phenyl]ethylidene]bis[4,1-phenyleneoxymethylene]]bis- (P-15-356, Chemical A); and 2-Propanol, 1,3-bis[4-[1-[4-[1-methyl-1-[4-(2-oxiranylmethoxy)phenyl]ethyl]phenyl]-1-[4-(2-oxiranylmethoxy)phenyl]ethyl]phenoxy]- (P-15-356, Chemical B).	115254-47-2 (P-15-356, Chemical A) and 188063-56-3 (P-15-356, Chemical B).	CBI	March 20, 2015	N/A	N/A	August 11, 2015	144	May 16, 2016	N/A	July 15, 2016	483	No	N/A	N/A	The PMN states that the substances will be used as additives in polymer formulation for electronics. Based on test data on the PMN substances and on SAR analysis of test data on analogous epoxides, EPA identified concerns for respiratory sensitization and irritation, mutagenicity, developmental toxicity, male reproduction toxicity, liver and kidney toxicity, and oncogenicity. Additionally, based on SAR analysis of test data on analogous polyepoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances in surface waters. Further, EPA has concerns that the PMN substances are potentially PBT chemicals as described in the New Chemical Program's PBT category (64 FR 60194, November 4, 1999) (FRL-6097-7). EPA estimates that the PMN substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 3,000. For the use described in the PMN, EPA expects occupational exposures to be minimal and does not expect releases to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as additives in polymer formulations for electronics or any use of the substances resulting in releases to surface waters may cause serious human health or significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(1)(i)(C), (b)(3)(i), (b)(3)(ii), and (b)(4)(i).	Recommended testing: EPA has determined that the results of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD Test Guideline 422); a sediment-water chironomid life-cycle toxicity test (OECD Test Guideline 233), using spiked water or spiked sediment; a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substances.	40 CFR 721.10910 (P-15-356, chemical A) and 40 CFR 721.10911 (P-15-356, chemical B) 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 22512 (April 22, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-22/pdf/2015-09204.pdf

P-15-363	Aliphatic acrylate (generic).	Claimed confidential.	CBI	March 23, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	480	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a monomer. Based on SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substance	40 CFR 721.10912 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 22512 (April 22, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-22/pdf/2015-09204.pdf
P-15-378	Diisocyanato hexane, homopolymer, alkanoic acid-polyalkylene glycol ether with substituted alkane (3:1) reaction products-blocked (generic).	Claimed confidential.	Allnex USA, Inc	April 3, 2015	N/A	N/A	August 31, 2015	150	May 16, 2016	N/A	July 15, 2016	469	No	N/A	N/A	The PVN states that the substance will be used as a dual-cure/UV cure adhesion/barrier coating for wood substrates. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization. As described in the PVN, EPA does not expect significant occupational dermal or inhalation exposure due to use of adequate personal protective equipment and consumer exposures are not expected as the PVN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PVN substance.	40 CFR 721.10913 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 31371 (June 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-02/pdf/2015-13418.pdf
P-15-382	Polytaconic acid, sodium zinc salt (generic).	Claimed confidential	CBI	April 3, 2015	N/A	N/A	April 29, 2016	392	May 16, 2016	N/A	July 15, 2016	469	No	N/A	N/A	The PVN states that the substance will be used as an odor neutralization for pet litter and cleaning hard surface surfaces, fabrics, skin and hair; an odor neutralization for air car; and an odor neutralization for waste processing and solid waste management in paper, oil, gas, mining, agriculture, food and municipal industries. Based on SAR analysis of test data on analogous zinc salts, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PVN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PVN, exceed releases from the use described in the PVN. For the use described in the PVN, environmental releases did not exceed 4 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PVN may result in significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substance .	40 CFR 721.10914 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 31371 (June 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-02/pdf/2015-13418.pdf
P-15-411	Fatty acid esters with polyols polyalkyl ethers (generic)	Claimed confidential	CBI	April 15, 2015	N/A	N/A	September 7, 2015	145	May 16, 2016	N/A	July 15, 2016	457	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as an anti-rust coating solution additive. Based on SAR analysis of test data on analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 30 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 30 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 30 ppb may result in significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10915 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 31371 (June 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-02/pdf/2015-13418.pdf
P-15-435	2,7-Naphthalenedisulfonic acid, 4-amino-3-[substituted]-5-hydroxy-6-[(1E)-2-phenyldiazenyl]-, lithium salt (1:3) (generic).	Claimed confidential.	CBI	April 27, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	445	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a direct anionic dyestuff for the printing industry. Based on the results of a 28-day oral study for the PVN substance, EPA predicts anemia, effects on the adrenals, spleen, kidney, lymph nodes and immunotoxicity. In addition, based on the lithium salt of the PVN, EPA identified concerns for developmental toxicity and neurotoxicity. Further, based on SAR analysis of test data on analogous azo dyestuffs products, EPA identified concerns for blood effects, developmental toxicity, oncogenicity, and mutagenicity. As described in the PVN, EPA does not expect significant risk to workers due to use of adequate personal protective equipment. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than in a liquid formulation could result in exposures which may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(1)(i)(C), (b)(3)(i) and (b)(3)(ii).	Recommended testing: EPA has determined that the results of an ames assay (OPPTS Test Guideline 870.5100) with the rival modification; a mouse micronucleus assay conducted by the oral route (OPPTS Test Guideline 870.5395); and a combined repeated dose and developmental toxicity and reproductive toxicity screening test (OPPTS Test Guideline 870.3650) would help to characterize the health effects of the PVN substance.	40 CFR 721.10916 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 31371 (June 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-02/pdf/2015-13418.pdf
P-15-502	Perfluorobutanesulfonamide and polyoxyalkylene containing polyurethane (generic).	Claimed confidential	CBI	June 2, 2015	November 4, 2015	155	January 8, 2016	220	May 16, 2016	194	July 15, 2016	409	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a protective treatment. EPA has concerns for potential incineration or other decomposition products of the PVN substance. These fluorinated decomposition products may be released to the environment from incomplete incinerations of the PVN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers which suggest that under some conditions, the PVN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including PFOA and other perfluorinated alkyls, including the presumed environmental degradant. EPA also has concerns that under some conditions of use, particularly non-industrial, commercial, or consumer use, the PVN substance could cause lung effects, based on limited data on some perfluorinated compounds. Concerns for the PVN substance are for lung toxicity from waterproofing of lung membrane, based on PVN properties. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that the substance and its potential intermediate and/or ultimate degradation products may present an unreasonable risk of injury to the environment and human health.	Recommended testing: EPA has determined that the results of an aerobic and anaerobic transformation in soil test (OECD Test Guideline 307) would help characterize the possible degradation of the PMN substance. The submitter has agreed to submit the results of this test by the confidential production volume identified in the consent order. EPA had determined that the results of a phototransformation of chemicals on soil surfaces (OECD Draft Document January 2002) would help characterize the degradation potential of the PMN substance. The Order does not require this testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10918 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 48855 (August 14, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-08-14/pdf/2015-20018.pdf
P-15-542	Quaternary ammonium compounds, (3-chloro-2-hydroxypropyl)coco alkyldimethyl, chlorides	690995-44-9	Colonial Chemical, Inc	June 18, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	393	No	N/A	N/A	The PMN states that the substance will be used as an intermediate for surfactant production, and as a chemical intermediate for sale into commerce. Based on SAR analysis of test data on analogous cationic (quaternary ammonium) surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 24 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 24 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 24 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10919 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 48855 (August 14, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-08-14/pdf/2015-20018.pdf
P-15-559	Modified diphenylmethane diisocyanate prepolymer with polyol (generic).	Claimed confidential	CBI	June 29, 2015	N/A	N/A	October 20, 2015	113	May 16, 2016	N/A	July 15, 2016	382	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a raw material for flexible foam. Based on SAR analysis of analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PVN substance where the average molecular weight is below 7,500 daltons and any molecular weight species is below 1,000 daltons. For the molecular weight distribution described in the PVN, significant occupational exposures are not expected. Therefore, EPA has not determined that the proposed manufacture of the substance may present an unreasonable risk. EPA has determined, however, that any manufacture of the PVN substance with an average molecular weight below 7,500 daltons, and where any molecular weight species is below 1,000 daltons may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.	40 CFR 721.10920 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 48855 (August 14, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-08-14/pdf/2015-20018.pdf
P-15-573	2-Furancarboxyaldehyde, 5-(chloromethyl)-	1623-88-7	Xf Technologies	July 6, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	375	No	N/A	N/A	The PVN states that the use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on analogous aldehydes, the EPA identified human health concerns for liver toxicity, neurotoxicity, sensitization, and cancer to workers exposed through dermal and inhalation routes. For the chemical intermediate use described in the PVN, occupational exposures are expected to be minimal due to the use of adequate personal protective equipment and a continuous reaction process such that no greater than 50 kilograms of the PMN substance is present in the workplace at a given time for this use. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use without the use of a NIOSH-certified respirator with an APF of at least 50, where there is a potential for inhalation exposures; any use without the use of impervious gloves, where there is a potential for dermal exposures, any use of the substance other than as a chemical intermediate; or any use beyond the annual production volume limit of 15,000 kilograms may result in serious human health or significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(1)(i)(C) and (b)(3)(ii).	Recommended testing: EPA has determined that the results of a skin sensitization (OECD Test Guideline 406) would help characterize the human health effects of the PMN substance; a combined repeated dose toxicity test with the reproduction/developmental toxicity screening test (OECD Test Guideline 422) with functional observational battery (FOB); a standard test method for permeation of liquids and gases through protective clothing materials under conditions of continuous contact (ASTM Test Guideline F739) using the format specified in the standard guide for documenting the results of chemical permeation testing of materials used in protective clothing materials (ASTM Test Guideline F1194-99(2010)); and a carcinogenicity test (OECD Test Guideline 451) would help characterize the human health effects of the PMN substance.	40 CFR 721.10921 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-607	1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(alkyl) derivs. (generic).	Claimed confidential	CBI	July 14, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	367	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an initiator for polymerization. Based on data on the PMN substance, as well as SAR analysis of test data on analogous peroxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 56 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 56 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) using a solvent where the effects of the solvent are already known or measured, would help characterize the environmental effects of the PMN substance.	40 CFR 721.10922 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 55613 (September 16, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-16/pdf/2015-23297.pdf
P-15-671	9-Octadecen-1-amine, hydrochloride (1:1), (9Z)-	41130-29-4	Tri-State Asphalt, LLC	August 5, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	345	No	N/A	N/A	The PVN states that the substance will be used as an emulsifying agent used in the production of asphalt emulsions for chipsealing and other road maintenance techniques. Based on test data for the PMN substance, as well as SAR analysis of test data on analogous alliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10923 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 64409 (October 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-27031.pdf
P-15-689	Vegetable fatty acid alkyl esters (generic).	Claimed confidential	CBI	August 17, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	333	No	N/A	N/A	The PVNs state that the substances will be used as chemical intermediates. Based on SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substances to surface water exceeds releases from the use described in the PVN. For the chemical intermediate use described in the PVN, environmental releases did not exceed 1 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as an intermediate may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help to characterize the environmental effects of the PVN substances. Depending on the results of these tests, EPA has determined that the results of an aerobic and anaerobic metabolism test (OECD Test Guideline 308) in aquatic sediment systems test; and a sediment water chironomid life-cycle toxicity test (OECD Test Guideline 233) using spiked water or spiked sediment would help to further characterize the environmental effects of the PVN substances.	40 CFR 721.10924 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 64409 (October 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-27031.pdf
P-15-690	Vegetable fatty acid alkyl esters (generic).	Claimed confidential	CBI	August 17, 2015	N/A	N/A	N/A	N/A	May 16, 2016	N/A	July 15, 2016	333	No	N/A	N/A	The PVNs state that the substances will be used as chemical intermediates. Based on SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substances to surface water exceeds releases from the use described in the PVN. For the chemical intermediate use described in the PVN, environmental releases did not exceed 1 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as an intermediate may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help to characterize the environmental effects of the PVN substances. Depending on the results of these tests, EPA has determined that the results of an aerobic and anaerobic metabolism test (OECD Test Guideline 308) in aquatic sediment systems test; and a sediment water chironomid life-cycle toxicity test (OECD Test Guideline 233) using spiked water or spiked sediment would help to further characterize the environmental effects of the PVN substances.	40 CFR 721.10924 81 FR 30451 (May 16, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11121.pdf	80 FR 64409 (October 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-27031.pdf
P-15-221	Isocyanate prepolymer (generic).	Claimed confidential	CBI	January 22, 2015	N/A	N/A	N/A	N/A	April 13, 2016	N/A	N/A (adverse comments received)	N/A	Yes	April 13, 2016	No final SNUR yet	The PVN states that the generic (non-confidential) use of the substance will be as ingredient in an industrial adhesive. Based on Structure Activity Relationship (SAR) analysis of test data on analogous diisocyanates, EPA identified concerns for irritation and sensitization to the skin and lungs. As described in the PVN, EPA does not expect significant occupational dermal or inhalation exposure due to use of adequate personal protective equipment and consumer exposures are not expected as the PVN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a National Institute for Occupational Safety and Health (NIOSH)-certified particulate respirator with an Assigned Protection Factor (APF) of at least 10 where there is a potential for inhalation exposure, or any use in consumer products may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.	No CFR (no final rule) Proposed rule: 81 FR 21830 (April 13, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-04-13/pdf/2016-08511.pdf	80 FR 14374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-247	Methylene diisocyanate polymer with diols and triols (generic).	Claimed confidential	H.B. Fuller Company	January 29, 2015	N/A	N/A	N/A	N/A	April 13, 2016	N/A	N/A (adverse comments received)	N/A	Yes	April 13, 2016	No final SNUR yet	The PVN states that the generic (non-confidential) use of the substance will be as an industrial adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety. As described in the PVN, EPA does not expect significant occupational dermal or inhalation exposure due to use of adequate personal protective equipment and consumer exposures are not expected as the PVN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products, may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PVN substance.	No CFR (no final rule) Proposed rule: 81 FR 21830 (April 13, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-04-13/pdf/2016-08511.pdf	80 FR 14374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-278	Polymer of isophorone diisocyanate and amine-terminated propoxylated polyol (generic)	Claimed confidential.	CBI	February 6, 2015	N/A	N/A	N/A	N/A	April 13, 2016	N/A	N/A (adverse comments received)	N/A	Yes	April 13, 2016	No final SNUR yet	The PVN states that the generic (non-confidential) use of the substance will be as a crosslinker. Based on analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures and for pulmonary toxicity from inhalation exposure to the PVN substance when the average molecular weight is below 2,500 daltons and any molecular weight species below 1,000 daltons is present. EPA does not expect significant exposures from the form of the PVN substance as described in the PVN. Therefore, EPA has not determined that the proposed manufacture of the substance may present an unreasonable risk. EPA has determined, however, that any manufacture of the PVN substance with an average molecular weight of below 2,500 daltons and with any molecular weight species below 1,000 daltons may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PVN substance.	No CFR (no final rule) Proposed rule: 81 FR 21830 (April 13, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-04-13/pdf/2016-08511.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf
P-12-539	Alkanes, C21-34—branched and linear, chloro	1417900-96-9	Trinity Manufacturing, Inc	September 1, 2012	March 19, 2013	199	May 16, 2013	257	February 12, 2016	1060	N/A (adverse comments received)	N/A	Yes	February 10, 2014	April 12, 2016	The PVNs state that the uses of the substances are as flame retardants/plasticizers in polymers and extreme pressure lubricants in metal working fluids (MWFs). There are also several CBI uses that are generically described as: Plasticizer and lubricant with flame retardant properties. By analogy to medium chain chlorinated paraffins (MCCPs—alkyl chain length of 14 to 17), EPA expects very long chain chlorinated paraffins (vLCCPs) and possible degradation products to be potentially highly persistent, potentially bioaccumulative, and potentially toxic. Transport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans. EPA has concerns about the potential for the vLCCPs to degrade to shorter chain chlorinated compounds, as well as concerns about potential impurities or small fractions of MCCPs and/or long-chain chlorinated paraffins (LCCPs—alkyl chain length of 18 to 20). The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposures to the PMN substances.	Recommended testing: EPA has determined that analysis for chain length and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry (GC/MS HPLC/MS)); a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.3280), modified SCAS test for insoluble and volatile chemicals (OPPTS Test Guideline 835.5045), or Zahn Wellens/EMPA test (OPPTS Test Guideline 835.3200); aerobic and anaerobic soil metabolism studies (Organisation for Economic Co-operation and Development (OECD) Test Guideline 307); a bioaccumulation in sediment-dwelling benthic oligochaetes test (OECD Test Guideline 315) on the PMN substances and their potential degradation products; and a sediment water chironomid life-cycle toxicity test using spiked water or spiked sediment test (OECD Test Guideline 233) or a sediment-water lumbriculus toxicity test using spiked sediment (OECD Test Guideline 225) on the PMN substances and their presumed degradation products would help characterize the effects of the PMN substances	40 CFR 721.10673 81 FR 7455 (February 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02952.pdf	77 FR 61600 (October 10, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-10-10/pdf/2012-24772.pdf

P-13-107	Alkanes, C22-30—branched and linear, chloro	1401947-24-0	Trinity Manufacturing, Inc.	November 14, 2012	March 19, 2013	125	January 28, 2014	440	February 12, 2016	1060	N/A (adverse comments received)	N/A	Yes	February 10, 2014	April 12, 2016	The PMNs state that the uses of the substances are as flame retardants/plasticizers in polymers and extreme pressure lubricants in metal working fluids (MWFs). There are also several CBI uses that are generically described as: Plasticizer and lubricant with flame retardant properties. By analogy to medium chain chlorinated paraffins (MCCPs—alkyl chain length of 14 to 17), EPA expects very long chain chlorinated paraffins (vLCCPs) and possible degradation products to be potentially highly persistent, potentially bioaccumulative, and potentially toxic. Transport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans. EPA has concerns about the potential for the vLCCPs to degrade to shorter chain chlorinated compounds, as well as concerns about potential impurities or small fractions of MCCPs and/or long-chain chlorinated paraffins (LCCPs—alkyl chain length of 18 to 20). The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposures to the PMN substances	Recommended testing: EPA has determined that analysis for chain length and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry (GC/MS, HPLC/MS)); a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.3220), modified SCAS test for insoluble and volatile chemicals (OPPTS Test Guideline 835.5041), or Zahn Wellens/EMPA test (OPPTS Test Guideline 835.3200); aerobic and anaerobic soil metabolism studies (Organisation for Economic Co-operation and Development (OECD) Test Guideline 307); a bioaccumulation in sediment-dwelling benthic oligochaetes test (OECD Test Guideline 315) on the PMN substances and their potential degradation products; and a sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment test (OECD Test Guideline 233) or a sediment-water lumbriculus toxicity test using spiked sediment (OECD Test Guideline 225) on the PMN substances and their presumed degradation products would help characterize the effects of the PMN substances.	40 CFR 721.10674 81 FR 7455 (February 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02952.pdf	77 FR 76029 (December 26, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-31063.pdf
P-13-109	Alkanes, C24-28, chloro	1402738-52-6	Trinity Manufacturing, Inc.	November 14, 2012	March 19, 2013	125	April 15, 2013	152	February 12, 2016	1060	N/A (adverse comments received)	N/A	Yes	February 10, 2014	April 12, 2016	The PMNs state that the uses of the substances are as flame retardants/plasticizers in polymers and extreme pressure lubricants in metal working fluids (MWFs). There are also several CBI uses that are generically described as: Plasticizer and lubricant with flame retardant properties. By analogy to medium chain chlorinated paraffins (MCCPs—alkyl chain length of 14 to 17), EPA expects very long chain chlorinated paraffins (vLCCPs) and possible degradation products to be potentially highly persistent, potentially bioaccumulative, and potentially toxic. Transport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans. EPA has concerns about the potential for the vLCCPs to degrade to shorter chain chlorinated compounds, as well as concerns about potential impurities or small fractions of MCCPs and/or long-chain chlorinated paraffins (LCCPs—alkyl chain length of 18 to 20). The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposures to the PMN substances	Recommended testing: EPA has determined that analysis for chain length and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry (GC/MS, HPLC/MS)); a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.3220), modified SCAS test for insoluble and volatile chemicals (OPPTS Test Guideline 835.5041), or Zahn Wellens/EMPA test (OPPTS Test Guideline 835.3200); aerobic and anaerobic soil metabolism studies (Organisation for Economic Co-operation and Development (OECD) Test Guideline 307); a bioaccumulation in sediment-dwelling benthic oligochaetes test (OECD Test Guideline 315) on the PMN substances and their potential degradation products; and a sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment test (OECD Test Guideline 233) or a sediment-water lumbriculus toxicity test using spiked sediment (OECD Test Guideline 225) on the PMN substances and their presumed degradation products would help characterize the effects of the PMN substances.	40 CFR 721.10675 81 FR 7455 (February 12, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02952.pdf	77 FR 76029 (December 26, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-31063.pdf
P-12-69	Fatty acids compound with cyclohexanamine (generic)	Claimed Confidential	CBI	November 15, 2011	February 11, 2015	1184	N/A	N/A	October 2, 2015	233	December 1, 2015	1477	No	N/A	N/A	The PMNs states that the generic (non-confidential) use of the substances will be as a lubricity additive (P-12-69 and P-12-70) and a chemical component for fuel additives (P-12-520). Based on structure-activity relationship (SAR) analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms to occur at concentrations that exceed 52 parts per billion (ppb) (P-12-69), 4 ppb (P-12-70) and 180 ppb (P-12-520) of the PMN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMNs, exceed releases from the use described in the PMNs. For the uses described in the PMNs, environmental releases did not exceed 52 ppb, 4 ppb, or 180 ppb, respectively, for more than 20 days per year. The consent order for these PMN substances was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the uncontrolled manufacture, processing, distribution in commerce, use and disposal may present an unreasonable risk to the environment. To protect against these risks, the consent order requires manufacturing, processing, or use of the substance for the specific confidential uses stated in the PMNs. The SNUR designates as a "significant new use" the absence of these protective measures.	Recommended testing: EPA has determined that the results of a fish early life-stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnia chronic toxicity test (OPPTS 850.1300) would help characterize the environmental effects of the PMN substances. Testing should be done on P-12-69 only. The submitter has agreed not to exceed a confidential volume limit without performing this testing.	CFR 721.10852 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	77 FR 5091 (February 1, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-02-01/pdf/2012-1922.pdf
P-12-70	Fatty acids compound with cyclohexanamine (generic)	Claimed Confidential	CBI	November 15, 2011	February 11, 2015	1184	July 7, 2017	2061	October 2, 2015	233	December 1, 2015	1477	No	N/A	N/A	The PMNs states that the generic (non-confidential) use of the substances will be as a lubricity additive (P-12-69 and P-12-70) and a chemical component for fuel additives (P-12-520). Based on structure-activity relationship (SAR) analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms to occur at concentrations that exceed 52 parts per billion (ppb) (P-12-69), 4 ppb (P-12-70) and 180 ppb (P-12-520) of the PMN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMNs, exceed releases from the use described in the PMNs. For the uses described in the PMNs, environmental releases did not exceed 52 ppb, 4 ppb, or 180 ppb, respectively, for more than 20 days per year. The consent order for these PMN substances was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the uncontrolled manufacture, processing, distribution in commerce, use and disposal may present an unreasonable risk to the environment. To protect against these risks, the consent order requires manufacturing, processing, or use of the substance for the specific confidential uses stated in the PMNs. The SNUR designates as a "significant new use" the absence of these protective measures.	Recommended testing: EPA has determined that the results of a fish early life-stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnia chronic toxicity test (OPPTS 850.1300) would help characterize the environmental effects of the PMN substances. Testing should be done on P-12-69 only. The submitter has agreed not to exceed a confidential volume limit without performing this testing.	CFR 721.10852 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	77 FR 5091 (February 1, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-02-01/pdf/2012-1922.pdf
P-12-520	Fatty acids amine salt (generic)	Claimed Confidential	CBI	August 21, 2012	February 11, 2015	904	N/A	N/A	October 2, 2015	233	December 1, 2015	1197	No	N/A	N/A	The PMNs states that the generic (non-confidential) use of the substances will be as a lubricity additive (P-12-69 and P-12-70) and a chemical component for fuel additives (P-12-520). Based on structure-activity relationship (SAR) analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms to occur at concentrations that exceed 52 parts per billion (ppb) (P-12-69), 4 ppb (P-12-70) and 180 ppb (P-12-520) of the PMN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMNs, exceed releases from the use described in the PMNs. For the uses described in the PMNs, environmental releases did not exceed 52 ppb, 4 ppb, or 180 ppb, respectively, for more than 20 days per year. The consent order for these PMN substances was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that the uncontrolled manufacture, processing, distribution in commerce, use and disposal may present an unreasonable risk to the environment. To protect against these risks, the consent order requires manufacturing, processing, or use of the substance for the specific confidential uses stated in the PMNs. The SNUR designates as a "significant new use" the absence of these protective measures.	Recommended testing: EPA has determined that the results of a fish early life-stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnia chronic toxicity test (OPPTS 850.1300) would help characterize the environmental effects of the PMN substances. Testing should be done on P-12-69 only. The submitter has agreed not to exceed a confidential volume limit without performing this testing.	40 CFR 721.10856 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	77 FR 61600 (October 10, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-10-10/pdf/2012-24772.pdf
P-12-169	Fluoro-modified acrylic copolymer (generic).	Claimed confidential.	CBI	January 26, 2012	March 19, 2015	1148	November 18, 2015	1392	October 2, 2015	197	December 1, 2015	1405	No	N/A	N/A	The PMN states that the use of the substance will be as a substrate wetting and leveling agent for organic solvent-based paints and inks. EPA has concerns for potential incineration or other decomposition products of the PMN substance. These fluorinated decomposition products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain physical/chemical property and environmental fate testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substance and its degradation products. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. Further, EPA has identified certain toxicity and environmental fate testing described in the Pended Testing section of the Preamble to the Order that would help characterize the possible effects of the PMN substance. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10853 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	77 FR 10512 (February 22, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-02-22/pdf/2012-4069.pdf
P-12-351	Siloxanes and Silicones, alkyl, alkyl propoxy ethyl, methyl octyl, alkyl polyfluorooctyl (generic).	Claimed confidential	CBI	May 10, 2012	March 19, 2015	1043	N/A	N/A	October 2, 2015	197	December 1, 2015	1300	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a coating additive. EPA has concerns for potential incineration or other decomposition products of the PMN substance. These fluorinated decomposition products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	Recommended testing: EPA has determined that the results of certain physical/chemical property and environmental fate testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substances and their degradation products. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. Further, EPA has identified certain toxicity and environmental fate testing described in the Pended Testing section of the Preamble to the Order that would help characterize the effects of the PMN substances. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10854 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	77 FR 40033 (July 6, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-07-06/pdf/2012-16453.pdf
P-12-450	Partially fluorinated alcohol, reaction products with phosphorus oxide (P 2 O 5), amine salts (generic).	Claimed confidential	CBI	July 8, 2012	March 16, 2015	981	October 1, 2015	1180	October 2, 2015	200	December 1, 2015	1241	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as coating additives and surface active agents. EPA has concerns for potential incineration or other decomposition products of the PMN substances. These perfluorinated decomposition products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposures to the substances and their potential degradation products.	EPA has determined that the results of certain physical/chemical property and environmental fate testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substances and their degradation products. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. Further, EPA has identified certain toxicity and environmental fate testing described in the Pended Testing section of the Preamble to the Order that would help characterize the effects of the PMN substances. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10855 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	77 FR 48976 (August 15, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-08-15/pdf/2012-20035.pdf
P-12-451	Partially fluorinated alcohol, reaction products with phosphorus oxide (P 2 O 5), amine salts (generic).	Claimed confidential	CBI	July 8, 2012	March 16, 2015	981	N/A	N/A	October 2, 2015	200	December 1, 2015	1241	No	N/A	N/A	The PMNs state that the generic (non-confidential) use of the substances will be as coating additives and surface active agents. EPA has concerns for potential incineration or other decomposition products of the PMN substances. These perfluorinated decomposition products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products.	EPA has determined that the results of certain physical/chemical property and environmental fate testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substances and their degradation products. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. Further, EPA has identified certain toxicity and environmental fate testing described in the Pended Testing section of the Preamble to the Order that would help characterize the effects of the PMN substances. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10855 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	77 FR 48976 (August 15, 2012) https://www.gpo.gov/fdsys/pkg/FR-2012-08-15/pdf/2012-20035.pdf
P-13-292	Organophosphorus polymer (generic).	Claimed confidential.	CBI	February 18, 2013	February 13, 2015	725	N/A	N/A	October 2, 2015	231	December 1, 2015	1016	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an additive for polymers. Using available exposure information from the public literature (i.e., measured values for similar substances in house dust in homes), and certain assumptions for mouthing behavior by young children, EPA identified concerns for potential exposure to the general population. However, there is uncertainty about the risk from this scenario due to the absence of information on the PMN substance itself and information on the ability for the PMN substance to migrate or leach out of certain consumer products. Consumer exposure is possible if the PMN migrates from these products or decomposes to form dust particles that can be inhaled or ingested. Analogous chemicals, including Tris(2-chloroethyl)phosphate (TCEP) and Tris(1,3-dichloro-2-propyl) phosphate (TDCPP), can be found in household dust, and are widespread in the environment. Assuming similar use patterns over time, the PMN substance may be expected to display similar exposure patterns. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(II), based on a finding that this substance may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities and human health. The substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. To address potential exposures and hazards, the consent order requires certain testing by certain confidential production volume limits	Recommended testing: EPA has determined that the results of certain physical/chemical property, toxicity, potential for migration from products, and dermal and other absorption testing identified in the TSCA 5(e) consent order would help characterize possible effects of the substance. The Order prohibits the Company from exceeding specified confidential production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.	40 CFR 721.10857 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	78 FR 28586 (May 15, 2013) https://www.gpo.gov/fdsys/pkg/FR-2013-05-15/pdf/2013-11507.pdf
P-13-305	Fluorinated acid alkylester (generic).	Claimed confidential.	3M Company—group compilance 3m automotive and chemical markets group	February 21, 2013	February 27, 2015	736	March 10, 2015	747	October 2, 2015	217	December 1, 2015	1013	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an intermediate. EPA has concerns that the PMN substance will persist in the environment, could bioaccumulate, and be toxic ("PBT") to humans, other mammals, and birds. EPA's concerns are based on data on the PMN substance, and analogy to perfluorobutanoic acid (PFBA), PFOA, perfluorooctanoic sulfonate (PFOS), and other analogs. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that this substance may present an unreasonable risk of injury to the environment and human health.	Recommended testing: EPA has determined that the results of certain toxicity, metabolism and pharmacokinetics testing described in the Pended Testing section of the Preamble to the Order would help characterize the human health effects of the PMN substance. The Order does not require submission of the pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.	40 CFR 721.10858 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	78 FR 28586 (May 15, 2013) https://www.gpo.gov/fdsys/pkg/FR-2013-05-15/pdf/2013-11507.pdf
P-14-563	Quaternary alkyl methyl amine ethoxylate methyl chloride (generic).	Claimed confidential.	CBI	May 19, 2014	N/A	N/A	January 26, 2016	617	October 2, 2015	N/A	December 1, 2015	561	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a cleaner/degreaser. Based on submitted test data on the PMN substance as well as SAR analysis of test data on analogous cationic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 29 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 29 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 29 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10859 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 55460 (September 16, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-16/pdf/2014-22037.pdf

P-14-756	Substituted carboxamide (generic).	Claimed confidential	CBI	July 30, 2014	N/A	N/A	February 11, 2015	287	October 2, 2015	N/A	December 1, 2015	580	No	N/A	N/A	The PVN states that the generic (non-confidential) use of the substance will be as a material for highly dispersive use in consumer products and component of a consumer product. Based on submitted test data on the PVN substance as well as SAR analysis of test data on analogous amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 3 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 3 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) and would help characterize the environmental effects of the PMN substance.	40 CFR 721.10860 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-14-804	Phosphoric acid, sodium titanium (4+) salt (3:1:2).	22239-24-3	CBI	August 22, 2014	N/A	N/A	July 10, 2015	322	October 2, 2015	N/A	December 1, 2015	466	No	N/A	N/A	The PMN states that the substance will be used as a component in anode material in sealed batteries. Based on SAR analysis of test data on analogous inorganic phosphates and titanium compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 4 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 4 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10861 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 56356 (September 19, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22282.pdf
P-15-1	Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate	73361-29-2	Croda	October 3, 2014	N/A	N/A	January 18, 2016	424	October 2, 2015	N/A	December 1, 2015	424	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as inert surfactants in pesticide formulations. Based on SAR analysis of test data on analogous anionic surfactant compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb in aggregate of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 18 ppb in aggregate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in aggregate releases to surface waters exceeding 18 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test (OCSPP Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The recommended testing may be performed on any one of the 6 PMN chemicals.	40 CFR 721.10862 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 68238 (November 14, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-11-14/pdf/2014-26903.pdf
P-15-2	Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, sodium salt	151688-56-1	Croda	October 3, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	424	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as inert surfactants in pesticide formulations. Based on SAR analysis of test data on analogous anionic surfactant compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb in aggregate of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 18 ppb in aggregate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in aggregate releases to surface waters exceeding 18 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The recommended testing may be performed on any one of the 6 PMN chemicals.	40 CFR 721.10862 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 68238 (November 14, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-11-14/pdf/2014-26903.pdf
P-15-3	Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, potassium salt	1456802-88-2	Croda	October 3, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	424	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as inert surfactants in pesticide formulations. Based on SAR analysis of test data on analogous anionic surfactant compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb in aggregate of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 18 ppb in aggregate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in aggregate releases to surface waters exceeding 18 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The recommended testing may be performed on any one of the 6 PMN chemicals.	40 CFR 721.10862 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 68238 (November 14, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-11-14/pdf/2014-26903.pdf
P-15-4	Oxirane, 2-methyl-, polymer with oxirane, monohexadecyl ether, phosphate, ammonium salt	1456802-89-3	Croda	October 3, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	424	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as inert surfactants in pesticide formulations. Based on SAR analysis of test data on analogous anionic surfactant compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb in aggregate of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 18 ppb in aggregate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in aggregate releases to surface waters exceeding 18 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The recommended testing may be performed on any one of the 6 PMN chemicals.	40 CFR 721.10862 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 68238 (November 14, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-11-14/pdf/2014-26903.pdf
P-15-5	Ethanol, 2-amino-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate	1456803-12-5	Croda	October 3, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	424	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as inert surfactants in pesticide formulations. Based on SAR analysis of test data on analogous anionic surfactant compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb in aggregate of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 18 ppb in aggregate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in aggregate releases to surface waters exceeding 18 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The recommended testing may be performed on any one of the 6 PMN chemicals.	40 CFR 721.10862 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 68238 (November 14, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-11-14/pdf/2014-26903.pdf
P-15-6	Ethanol, 2,2'2''-nitrilotris-, compd. with 2-methyloxirane polymer with oxirane monohexadecyl ether phosphate	1456803-14-7	Croda	October 3, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	424	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substances will be as inert surfactants in pesticide formulations. Based on SAR analysis of test data on analogous anionic surfactant compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb in aggregate of the PMN substances in surface waters. As described in the PMN, releases of the substances are not expected to result in surface water concentrations exceeding 18 ppb in aggregate. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances that results in aggregate releases to surface waters exceeding 18 ppb may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test (OPPTS Test Guideline 850.1010), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. The recommended testing may be performed on any one of the 6 PMN chemicals.	40 CFR 721.10862 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 68238 (November 14, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-11-14/pdf/2014-26903.pdf
P-15-25	Nitrile amine (generic).	Claimed confidential.	Akzo Nobel Surface Chemistry LLC	October 10, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	417	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a site-limited chemical intermediate. Based on submitted test data on the PVN substance as well as SAR analysis of test data on analogous neutral organic compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations exceeding 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i) and (ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10863 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-26	1,3-Propanediamine, N1, N1-alkyl (generic).	Claimed confidential	Akzo Nobel Surface Chemistry LLC	October 14, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	413	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a friction modifier. Based on submitted test data on an analogous substance as well as SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 32 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 32 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 32 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (Organisation for Economic Co-operation and Development (OECD) Test Guideline 23) be consulted to facilitate solubility in the test media, because of the PMN substance's low water solubility.	40 CFR 721.10864 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-36	2-Pyridinecarboxylic acid, 4,5,6 trichloro-	496849-77-5	CBI	October 16, 2014	N/A	N/A	September 1, 2015	320	October 2, 2015	N/A	December 1, 2015	411	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a chemical intermediate. Based on SAR analysis of test data on analogous pyridine-alpha-acids and neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 30 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations exceeding 30 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface water concentrations exceeding 30 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075), an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010), an algal toxicity test (OCSPP Test Guideline 850.4500), and the aerobic/anaerobic transformation in soil test (OECD 307) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10865 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-63	Imidazolium, polymer with cyclic anhydride and alkenoic acid, alkali salt (generic)	Claimed confidential	CBI	October 22, 2014	N/A	N/A	March 20, 2015	149	October 2, 2015	N/A	December 1, 2015	405	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a leather chemical. Based on SAR analysis of test data on analogous polyanionic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 200 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 200 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as listed in the PMN may result in significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a ready biodegradability test (OPPTS Test Guideline 835.3110), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10866 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	79 FR 73297 (December 10, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-12-10/pdf/2014-28944.pdf
P-15-98	Hydrochlorofluorocarbon (generic)	Claimed confidential	CBI	November 14, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	382	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an intermediate in the production of a hydrofluorocarbon (HFC). Based on SAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 99 ppb of the PMN substance in surface waters. Further, based on test data on analogous organohalogen compounds, there were health concerns regarding anesthesia at high inhalation doses from exposure to the PMN substance via dermal and inhalation exposure. As described in the PMN, exposure is expected to be minimal due to use of adequate dermal and respiratory personal protection equipment and releases of the substance are not expected to result in surface water concentrations exceeding 99 ppb. The refore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in releases to surface waters exceeding 99 ppb, or any use without the use of NIOSH-certified organic vapor cartridge respirator with an assigned protection factor of at least 25, or any use other than as a chemical intermediate may result in serious human health or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(4)(i).	Recommended testing: EPA has determined that the results of an acute inhalation toxicity test (OPPTS Test Guideline 870.1300), fish acute toxicity test (OPPTS Test Guideline 850.1075), an aquatic invertebrate acute toxicity test (OPPTS Test Guideline 850.1010), and algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance.	40 CFR 721.10867 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 3584 (January 23, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01173.pdf
P-15-136	Alkylalkenoic acid copolymer (generic)	Claimed confidential	CBI	December 11, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	355	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an encapsulating polymer. Based on test data on analogous high molecular weight polymers, EPA identified concerns for lung toxicity. As described in the PMN, EPA does not expect significant worker inhalation exposure due to no domestic manufacture, and the substance is not manufactured, processed, or used in the form of a powder. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any domestic manufacture of the substance or any import, processing, or use of the substance in the form of a powder may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test with a 60-day holding period (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.	40 CFR 721.10868 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 9262 (February 20, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-02-20/pdf/2015-03460.pdf
P-15-141	D-Glucitol, alkylamino-N-acyl derivs. (generic)	Claimed confidential	CBI	December 15, 2014	N/A	N/A	June 20, 2017	918	October 2, 2015	N/A	December 1, 2015	351	No	N/A	N/A	The PMN states that the substance will be used as a surfactant in cleaning products and liquid soaps. Based on test data on the PVN substance, as well as SAR analysis of test data on analogous nonionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 14 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 14 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 14 ppb may cause significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a ready biodegradability test (OECD Test Guideline 301) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10869 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 9262 (February 20, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-02-20/pdf/2015-03460.pdf
P-15-150	Cyclohexanedicarboxylic acid, dialkyl ester (generic)	Claimed confidential	Mitsui Chemicals America, Inc	December 17, 2014	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	349	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an adjuvant used in reaction processes. Based on SAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 10 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 10 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 10 ppb may cause significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10870 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 9262 (February 20, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-02-20/pdf/2015-03460.pdf
P-15-221	Isocyanate prepolymer (generic)	Claimed confidential.	CBI	January 22, 2015	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	313	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as ingredient in an industrial adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for irritation and sensitization to the skin and lungs. As described in the PVN, EPA does not expect significant occupational dermal or inhalation exposure due to use of adequate personal protective equipment and consumer exposures are not expected as the PVN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PVN substance.	40 CFR 721.10871 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 14374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-242	Heteropolycyclic, polymer with alkanedioic acid, di-alkenoate (generic).	Claimed confidential	CBI	January 27, 2015	N/A	N/A	May 7, 2015	100	October 2, 2015	N/A	December 1, 2015	308	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a coating resin. Based on test data on analogous acrylates, EPA identified concerns for oncogenicity, developmental toxicity, liver and kidney toxicity, sensitization, irritation, and acute toxicity. Further, based on SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 120 ppb of the PMN substance in surface waters. As described in the PMN, occupational exposures are expected to be minimal due to the use of impervious gloves, goggles, and NIOSH-certified particulate respirators with an APF of at least 10. Further, releases of the substance are not expected to result in surface water concentrations exceeding 120 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without use of impervious gloves and goggles, when there is a potential dermal exposure; use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10, where there is a potential for inhalation exposures; or any use of the substance that results in releases to surface waters exceeding 120 ppb may result in significant adverse health and environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(i), and (b)(4)(i).	Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OPPTS 870.3650); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PVN substance	40 CFR 721.10872 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 14374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-247	Methylene diisocyanate polymer with diols and triols (generic).	Claimed confidential	H.B. Fuller Company	January 29, 2015	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	306	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an industrial adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety As described in the PMN, EPA does not expect significant occupational dermal or inhalation exposure due to use of adequate personal protective equipment and consumer exposures are not expected as the PVN substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products, may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(i).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PVN substance.	40 CFR 721.10873 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 14374 (March 19, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-03-19/pdf/2015-06223.pdf
P-15-278	Polymer of isophorone diisocyanate and amine-terminated propoxylatedpolyol (generic)	Claimed confidential	CBI	February 6, 2015	N/A	N/A	N/A	N/A	October 2, 2015	N/A	December 1, 2015	298	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a cross linker. Based on analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PVN substance when the average molecular weight is below 2500 daltons and any molecular weight species is below 1000 daltons. EPA does not expect significant exposures from the form of the PVN substance as described in the PVN. Therefore, EPA has not determined that the proposed manufacture of the substance may present an unreasonable risk. EPA has determined, however, that any manufacture of the PVN substance with an average molecular weight of below 2500 daltons and any molecular weight species below 1000 daltons may cause serious health effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(3)(ii).	Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PVN substance.	40 CFR 721.10874 80 FR 59593 (October 2, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-24846.pdf	80 FR 18227 (April 3, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07495.pdf

P-13-793	Functionalized carbon nanotubes (generic)	Claimed confidential	CBI	August 2, 2013	N/A	N/A	November 19, 2014	474	June 10, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	No final SNUR yet -- EPA deferred action to a later date	The PVN states that the substance will be used as a thin film for electronic device applications. Based on SAR analysis of test data on analogous carbon nanotubes and other respirable poorly soluble particulates, EPA identified potential lung effects, developmental toxicity, and dermal toxicity from exposure to the PVN substance via inhalation, dermal, and oral routes. Further, EPA predicts toxicity to aquatic organisms via releases of the PVN substance to surface water. As described in the PVN, EPA does not expect significant occupational exposures due to the use of impervious gloves, where there is potential for dermal exposure, and because the PVN is used in liquid form and is not spray applied. Further, EPA does not expect environmental releases during the use identified in the PVN submission. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk human health or the environment. EPA has determined, however, that any use of the substance without the use of impervious gloves, where there is a potential for dermal exposure; manufacturing the PVN substance for use other than as a thin film for electronic device applications; manufacturing, processing, or using the PVN substance in a form other than a liquid; use of the PVN substance involving an application method that generates a mist, vapor, or aerosol; or any release of the PVN substance into surface waters may cause serious health effects or significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria in § 721.170(b)(3)(i) and (b)(4)(i).	Recommended testing: EPA has determined that the results of an oral and inhalation pharmacokinetic test (OPPTS Test Guideline 870.7485); a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); and a surface charge by electrophoresis by either the (ASTM Test Guideline E2865-12) or measuring the zeta potential of nanoparticles (Nanotechnology Characterization Library (NCL) Method PCC-2) (located in the Docket under Docket ID number EPA-HQ-OPPT-2014-0390); would help characterize the human health and environmental effects of the PVN substance.	No CFR (no final rule) Proposed rule: 80 FR 32879 (June 10, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-10/pdf/2015-13941.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-14-72	Propaneperoxoic acid, 2,2-dimethyl-, 1,1,3,3-tetramethylbutyl ester	22288-41-1	CBI	November 6, 2013	N/A	N/A	April 15, 2014	160	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PVN states that the use of the substance will be as a polymerization initiator for the production of polyvinyl chloride (PVC) and polyethylene resin. Based on test data on the PVN substance, as well as ecological SAR analysis of test data on analogous peroxy esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb of the PVN substance in surface waters. As described in the PVN, releases of the substance are not expected to result in surface water concentrations that exceed 3 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface waters concentrations exceeding 3 ppb may result in significant adverse environmental effects. Based on this information, the PVN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a ready biodegradability test (OECD Test Guideline 301C) with product-specific chemical analytics to validate the degradation products (including intermediate products) and the rates of degradation (including intermediate degradation rates); and a hydrolysis as a function of ph and temperature test (OPPTS Test Guideline 835.2130) would help characterize the environmental effects of the PVN substance.	40 CFR 721.10780 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-89	Fatty acid amide hydrochlorides (generic).	Claimed confidential	CBI	November 15, 2013	N/A	N/A	June 23, 2014	220	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The consolidated PVN states that the substances will be used as surfactants for use in asphalt emulsions. Based on ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 110 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10781 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-90	Fatty acid amide hydrochlorides (generic).	Claimed confidential	CBI	November 15, 2013	N/A	N/A	June 23, 2014	220	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	Basis for action: The consolidated PVN states that the substances will be used as surfactants for use in asphalt emulsions. Based on ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 240 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10781 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-91	Fatty acid amide hydrochlorides (generic).	Claimed confidential	CBI	November 15, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	Basis for action: The consolidated PVN states that the substances will be used as surfactants for use in asphalt emulsions. Based on ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 53 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10781 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-92	Fatty acid amide hydrochlorides (generic).	Claimed confidential	CBI	November 15, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The consolidated PVN states that the substances will be used as surfactants for use in asphalt emulsions. Based on ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 110 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PVN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10781 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-158	Fatty acid amides (generic).	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The consolidated PVN states that the substances will be used as chemical intermediates and additives for flotation products. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	EPA has determined that the results of (1) a water solubility: Column elution method; shake flask method test (OPPTS Test Guideline 830.7840) or a water solubility generator column method test (OPPTS Test Guideline 830.7860); and (2) a determination of the partition coefficient (n-octanol/water) by shake flask method (OPPTS Test Guideline 830.7550), or generator column method (OPPTS Test Guideline 830.7560), or estimation by liquid chromatography (OPPTS Test Guideline 830.7570) would help characterize the physical/chemical properties of the PVN substances. Depending upon the results of these data, the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test *63829 Guideline 850.4500) may be recommended to help characterize the environmental effects of the PVN substances.	40 CFR 721.10782 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-159	Fatty acid amides (generic).	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The consolidated PVN states that the substances will be used as chemical intermediates and additives for flotation products. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	EPA has determined that the results of (1) a water solubility: Column elution method; shake flask method test (OPPTS Test Guideline 830.7840) or a water solubility generator column method test (OPPTS Test Guideline 830.7860); and (2) a determination of the partition coefficient (n-octanol/water) by shake flask method (OPPTS Test Guideline 830.7550), or generator column method (OPPTS Test Guideline 830.7560), or estimation by liquid chromatography (OPPTS Test Guideline 830.7570) would help characterize the physical/chemical properties of the PVN substances. Depending upon the results of these data, the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test *63829 Guideline 850.4500) may be recommended to help characterize the environmental effects of the PVN substances.	40 CFR 721.10782 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-161	Fatty acid amides (generic).	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The consolidated PVN states that the substances will be used as chemical intermediates and additives for flotation products. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	EPA has determined that the results of (1) a water solubility: Column elution method; shake flask method test (OPPTS Test Guideline 830.7840) or a water solubility generator column method test (OPPTS Test Guideline 830.7860); and (2) a determination of the partition coefficient (n-octanol/water) by shake flask method (OPPTS Test Guideline 830.7550), or generator column method (OPPTS Test Guideline 830.7560), or estimation by liquid chromatography (OPPTS Test Guideline 830.7570) would help characterize the physical/chemical properties of the PVN substances. Depending upon the results of these data, the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test *63829 Guideline 850.4500) may be recommended to help characterize the environmental effects of the PVN substances.	40 CFR 721.10782 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-162	Fatty acid amides (generic).	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The consolidated PVN states that the substances will be used as chemical intermediates and additives for flotation products. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	EPA has determined that the results of (1) a water solubility: Column elution method; shake flask method test (OPPTS Test Guideline 830.7840) or a water solubility generator column method test (OPPTS Test Guideline 830.7860); and (2) a determination of the partition coefficient (n-octanol/water) by shake flask method (OPPTS Test Guideline 830.7550), or generator column method (OPPTS Test Guideline 830.7560), or estimation by liquid chromatography (OPPTS Test Guideline 830.7570) would help characterize the physical/chemical properties of the PVN substances. Depending upon the results of these data, the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test *63829 Guideline 850.4500) may be recommended to help characterize the environmental effects of the PVN substances.	40 CFR 721.10782 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-163	Fatty acid amides (generic).	Claimed confidential	CBI	December 16, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The consolidated PVN states that the substances will be used as chemical intermediates and additives for flotation products. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	EPA has determined that the results of (1) a water solubility: Column elution method; shake flask method test (OPPTS Test Guideline 830.7840) or a water solubility generator column method test (OPPTS Test Guideline 830.7860); and (2) a determination of the partition coefficient (n-octanol/water) by shake flask method (OPPTS Test Guideline 830.7550), or generator column method (OPPTS Test Guideline 830.7560), or estimation by liquid chromatography (OPPTS Test Guideline 830.7570) would help characterize the physical/chemical properties of the PVN substances. Depending upon the results of these data, the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test *63829 Guideline 850.4500) may be recommended to help characterize the environmental effects of the PVN substances.	40 CFR 721.10782 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-173	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PVNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PVN substances, would help characterize the environmental effects of the PVN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PVN P-14-184 would help characterize the environmental effects of the PVN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-175	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PVNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PVN substances, would help characterize the environmental effects of the PVN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PVN P-14-184 would help characterize the environmental effects of the PVN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-176	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PVNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PVN substances in surface waters: 1 ppb. For the use described in the PVNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PVN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PVN substances, would help characterize the environmental effects of the PVN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PVN P-14-184 would help characterize the environmental effects of the PVN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf

P-14-177	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 3 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-178	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 1 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-179	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 1 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-180	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 2 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-181	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 1 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-182	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 140 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-183	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 1 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-184	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 1 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-185	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	April 4, 2016 (reissued February 23, 2017)	839	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 2 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-186	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 2 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-187	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 2 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-188	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 3 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-190	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 2 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-191	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 4 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf

P-14-192	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 1 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-193	Fatty acid amide acetates (generic).	Claimed confidential	CBI	December 17, 2013	N/A	N/A	N/A	N/A	December 4, 2015	N/A	N/A (adverse comments received)	N/A	Yes	June 10, 2015	February 2, 2016	The PMNs state that the substances will be used as flotation additives for use in mineral processing. Based on ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the following values of the PMN substances in surface waters: 1 ppb. For the use described in the PMNs, releases of the substances are not expected to result in surface water concentrations that exceed these values. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding the aforementioned concentrations of concern may result in significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) on P-14-184, and any one of the remaining PMN substances, would help characterize the environmental effects of the PMN substances. Further, EPA determined that the results of a fish acute toxicity mitigated by humic acid test (OPPTS Test Guideline 850.1085) on PMN P-14-184 would help characterize the environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.	40 CFR 721.10783 80 FR 75812 (December 4, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-12-04/pdf/2015-30677.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-11-549	2-Butene, 1,1,1,4,4,4-hexafluoro-, (2Z)-	692-49-9	CBI	August 1, 2011	N/A	N/A	December 9, 2014	1226	June 5, 2015	N/A	August 4, 2015	1464	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a heat transfer fluid. Based on test data on the PMN substance as well as structure activity relationship (SAR) analysis of analogous small fluorinated compounds, EPA identified concerns for cardiac sensitization, developmental toxicity, neurotoxicity, reproductive toxicity and oncogenicity from inhalation exposures to the PMN substance. As described in the PMN, occupational exposures are expected to be minimal due to no domestic manufacture and consumer exposure is not expected due to no use of the substance in a consumer product. Therefore, EPA has not determined that the proposed processing or use of the substance may present an unreasonable risk. EPA has determined, however, that any domestic manufacture, any use other than as described in the PMN, or any use of the substance in a consumer product may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(3)(ii).	Recommended testing: EPA has determined that inhalation monitoring data, collected according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in the docket under docket ID number EPA-HQ-OPPT-2015-0220) would help characterize the human health effects of the PMN substance.	40 CFR 721.10830 80 FR 32003 (June 5, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13670.pdf	76 FR 58498 (September 21, 2011) https://www.gpo.gov/fdsys/pkg/FR-2011-09-21/pdf/2011-23973.pdf
P-13-660	Aluminum phosphate (generic).	Claimed confidential.	JJI Technologies, LLC	July 11, 2013	N/A	N/A	May 19, 2015	677	June 5, 2015	N/A	August 4, 2015	754	No	N/A	N/A	The PMN states that the substance will be used as a flame retardant for industrial plastics. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung effects, blood toxicity, hypersensitivity, developmental neurotoxicity, and immunotoxicity from inhalation exposures to the PMN substance. Further, based on ecological SAR analysis of test data on analogous aluminum salts, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 87 parts per billion (ppb) of the PMN substance in surface waters. As described in the PMN, occupational exposures are expected to be minimal due to use of respiratory protection, and releases of the substance are not expected to result in surface water concentrations that exceed 87 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the PMN substance without the use of National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 10, where inhalation exposures are expected, or any use of the substance resulting in surface water concentrations exceeding 87 ppb may cause serious human health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at 40 CFR 721.170(b)(3)(ii) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 413); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substance and mixtures (OECD Test Guideline 23) be consulted to facilitate solubility of the PMN substance in the test media.	40 CFR 721.10831 80 FR 32003 (June 5, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13670.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-13-872	Alkyl triazine (generic).	Claimed confidential	Lamberti USA	August 30, 2013	N/A	N/A	June 23, 2017	1393	June 5, 2015	N/A	August 4, 2015	704	No	N/A	N/A	The PMN states that the substance will be used in the removal of hydrogen sulfide. Based on test data on the PMN substance, as well as ecological SAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 130 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 130 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 130 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10832 80 FR 32003 (June 5, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13670.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-13-930	Substituted bis 2,6-xylenol (generic).	Claimed confidential	CBI	September 23, 2013	December 10, 2014	443	June 13, 2016	994	June 5, 2015	177	August 4, 2015	680	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a reactant in polymerization reactions. Based on SAR analysis of test data on structurally similar substances, EPA identified concerns for liver, kidney and developmental toxicity; blood effects, sensitization, and endocrine disruption. Further, based on test data on the PMN substance, EPA predicts toxicity to aquatic organism at concentrations that exceed 6 ppb of the PMN substance in surface waters. The order was issued under TSCA sections 5(e)(3)(A)(i) and 5(e)(3)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to the environment and human health, and there may be significant (or substantial) human exposure to the substance.	Recommended testing: EPA has determined that the results of certain toxicity testing, identified in the TSCA 5(e) consent order would help characterize possible effects of the substance. The submitter has agreed not to exceed the first confidential volume limit without performing an aromatase (human recombinant) test (OCSPP Test Guideline 890.1200) and a steroidogenesis (human cell line- H295R) test (OCSPP Test Guideline 890.1550 or OECD Test Guideline 456). Further, the Order prohibits the Company from exceeding the second confidential production volume limit unless the Company submits the Tier 2 testing described in the Testing section of this Order in accordance with the conditions specified in the Testing section.	40 CFR 721.10833 80 FR 32003 (June 5, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13670.pdf	79 FR 38288 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15760.pdf
P-14-20	Heteropolyacrylic diacrylate (generic).	Claimed confidential	Allnex USA Inc	October 17, 2013	N/A	N/A	November 10, 2014	389	June 5, 2015	N/A	August 4, 2015	656	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as a coating resin. Based on test data on the PMN, EPA identified concerns for dermal and ocular irritation, and systemic toxicity from the dermal, ocular, and oral routes. Further, based on ecological SAR analysis of test data on analogous acrylates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 120 ppb of the PMN substance in surface waters. As described in the PMN, occupational exposures are expected to be minimal due to the use of impervious gloves, goggles, and a NIOSH-certified particulate respirator with an APF of at least 10. Further, releases of the substance are not expected to result in surface water concentrations that exceed 120 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without the use of impervious gloves and goggles, when there is a potential dermal exposure; any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10, where there is a potential for inhalation exposures; or any use of the substance resulting in surface water concentrations exceeding 120 ppb may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i) and (b)(4)(i).	Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/developmental toxicity screening test (OPPTS Test Guideline 870.3650); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the human health and environmental effects of the PMN substance.	40 CFR 721.10834 80 FR 32003 (June 5, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13670.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-66	1,6-Hexanediamine, N1-(6-aminohexyl)-, polymer with 2-(chloromethyl)oxirane, N-(dithiocarboxy) derivs., sodium salts	1459738-70-5	Baze Chemical Company	November 6, 2013	N/A	N/A	N/A	N/A	June 5, 2015	N/A	August 4, 2015	636	No	N/A	N/A	The PMN states that the substance will be used as a water clarifier intermediate. Based on ecological SAR analysis of test data on analogous dithiocarbamates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance that results in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).	Recommended testing: EPA has determined that the results of a mysid acute toxicity test (OCSPP Test Guideline 850.1035); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an acute invertebrate toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10835 80 FR 32003 (June 5, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13670.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf
P-14-209	Dimethylaminoalkyl alkene amide (generic).	Claimed confidential.	CBI	December 26, 2013	N/A	N/A	N/A	N/A	June 5, 2015	N/A	August 4, 2015	586	No	N/A	N/A	The PMN states that the generic (non-confidential) use of the substance will be as an adjuvant for non-Federal insecticide, fungicide, and Rodenticide Act (FIFRA)-regulated agricultural use products, an additive for pesticide formulations, and an additive for fertilizer formulations. Based on test data on the PMN substance, as well as ecological SAR analysis of test data on analogous amides and aliphatic amines, EPA predicts chronic toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water exceed releases from the use described in the PMN. For the uses described in the PMN, environmental releases did not exceed the concentration of concern for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(i) and (b)(4)(ii).	Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.	40 CFR 721.10836 80 FR 32003 (June 5, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13670.pdf	79 FR 38302 (July 7, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-07-07/pdf/2014-15764.pdf

Comments of the American Chemistry Council on EPA's Implementation of the New Chemicals Review Program

Docket No. EPA-HQ-OPPT-2017-0585

January 19, 2018

Michael P. Walls
Karyn M. Schmidt
American Chemistry Council
700 Second Street, N.E.
Washington, DC 20002
(202) 249-7000

Of Counsel:
Mark N. Duvall
Timothy M. Serie
Beveridge & Diamond, P.C.
1350 I Street, N.W.
Washington, DC 20005
(202) 789-6000

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The American Chemistry Council (ACC)[1] welcomes the opportunity to provide comments on EPA's implementation of the New Chemicals Review Program under section 5 of the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[2] ACC submits these comments in response to EPA's notice announcing the December 5, 2017 public meeting on this subject and an opportunity to comment, 82 Fed. Reg. 51415 (Nov. 6, 2017).

These comments make the following points:

- The statutory framework for EPA's review of premanufacture notices (PMNs) for new chemical substances and its promulgation of significant new use rules (SNURs) was not fundamentally changed by LCSA. As before enactment, EPA must issue a section 5(e) order if it finds that a PMN substance "may present an unreasonable risk to health or the environment." If it does not make such a finding (or an alternative finding), EPA must allow the PMN submitter to commence non-exempt commercial manufacture. The LCSA did make three significant changes to this paradigm. First, risk findings are to be based solely on risks to health or the environment. Second, if choosing not to regulate a PMN substance, EPA must make an affirmative finding that the substance is "not likely to present an unreasonable risk," whereas before enactment EPA could effectively do so without explaining its reasoning in an affirmative finding. Third, certain findings must be made in consideration of the "conditions of use" of the PMN substance. Despite these changes, EPA continues to have authority to make decisions under section 5 essentially as it did prior to enactment. In particular, the addition of "conditions of use" has limited significance in the PMN context.

- In many cases, EPA is not meeting its statutory deadlines for completing its review of PMNs and consideration of SNURs. The delays that PMN submitters experience beyond those deadlines are contrary to the amended TSCA and to the Congressional priority for the introduction of new chemical substances into commerce once EPA review and regulatory action has been completed.

---

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an $812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

[2] Public Law 114-182 (June 22, 2016). References to TSCA in these comments are to TSCA as amended by the LCSA unless otherwise indicated.

- EPA's approach to making "may present" and "not likely to present" findings is not in accordance with the amended section 5.

- EPA should adopt a number of process improvements in the New Chemicals Review Process in order to meet its statutory deadlines and to streamline the administrative process. EPA should also consider improvements to the process for negotiating section 5(e) orders and provide greater transparency regarding its determinations under the New Chemicals Review Program.

- In deciding whether or not to issue a section 5(e) order, EPA has discretion to consider the "conditions of use" to be only the use, handling, and exposure conditions indicated in the PMN and the use, handling, and exposure conditions reasonably foreseeable from them. EPA should consider the "conditions of use" of subsequent manufacturers and processors in the context of a SNUR. EPA is not required to make a "may present" finding based on concerns that do not arise from the PMN, nor is it required to issue a section 5(e) order to the PMN submitter based solely on concerns arising outside the context of the PMN. In any case, such a section 5(e) order would be ineffective. Accordingly, EPA has statutory authority to promulgate "non-order" SNURs. However, EPA should make some important changes to the non-order SNUR process in order for it to work efficiently. In particular, EPA should issue its "not likely to present" finding after its review of the PMN is complete, following up with a SNUR as soon as practicable.

- EPA's Draft Points to Consider document and the New Chemicals Decision-Making Framework are helpful for PMN submitters, in that they provide increased insight into the internal workings of EPA's review process. EPA should consider making a number of revisions and additions to those documents.

- Additionally, EPA should consider making changes to the New Chemicals Review Program addressing chemical categories, low molecular weight species, worker health and safety requirements, and provisions relating to releases to water.

DISCUSSION

I. Review of the Legal Requirements for EPA's Determinations Under Section 5

EPA has revamped the New Chemicals Review Program in light of the LCSA's changes to section 5. Some stakeholders have argued that the revamping has not gone far enough, and others argue that it has gone too far. Both EPA's revisions to its Program and the stakeholder objections are driven by the statutory language and its legislative history. Accordingly, these comments begin with first principles: what section 5 now requires.

A. Overview of the New Section 5

Under section 5 as amended, EPA must make one of four determinations for a PMN substance within 90 days of submission of the PMN (subject to a possible one-time 90-day extension):

- The PMN substance "presents" an unreasonable risk.
- There is "insufficient" information for EPA to make a risk determination.
- There is insufficient information and the PMN substance "may present" an unreasonable risk.
- The PMN substance is "not likely to present" an unreasonable risk.

Risk determinations must take into account risks to potentially exposed or susceptible subpopulations. The risks evaluated must include only health or environmental risks; in making risk determinations, EPA must not consider cost or other nonrisk factors. In some cases, EPA must consider the "conditions of use" in making its risk evaluations.

If EPA makes a "not likely to present" determination, it must publish that determination, although the PMN submitter may commence non-exempt manufacture without waiting for that publication. If EPA makes any other determination, it must issue a section 5(e) order or take action under section 5(f). If it issues a section 5(e) order for a PMN substance, it must consider whether to promulgate a SNUR for the substance, and that consideration must be completed within 90 days of issuing the order.

B. The Fundamental Statutory Framework Has Not Changed

The first thing to observe is that the fundamental statutory framework remains in place. The LCSA amended some aspects of section 5, but it left intact the bulk of what EPA had in place beforehand based on the original TSCA.

1. Congress Did Not Call for Substantive Changes to Section 5

The legislative history reflects this judgement. During the legislative process, many stakeholders described EPA's New Chemicals Review Program as among the biggest successes of TSCA. The House bill that led to the LCSA, H.R. 2576, embraced that idea. As passed by the House of Representatives in 2015, it had no provision amending section 5.[3]

The Senate bill, S. 697, did include language amending section 5. However, the Senate Report on that bill had no criticism of EPA's New Chemicals Review Program, other than that it allowed EPA to make decisions not to regulate a PMN substance without explanation:

> Despite the completion of many reviews of new chemicals under section 5, concerns have been raised that it does not require EPA to make an affirmative finding that a new chemical or significant new use is not likely to present an unreasonable risk. [4]

The provision adding a requirement for EPA to make affirmative findings for its decisions not to regulate PMN substances reflected this desire for greater transparency, not any dissatisfaction

[3] H.R. 2576 (as passed by the House on June 23, 2015 by a vote of 398-1).
[4] S. Rep. No. 114-67, 114th Cong., 1st Sess. (June 18, 2015) (Senate Report) at 3.

with the review process itself.

2. EPA's Implementation of Section 5 Pre-Enactment Meant That No Substantive Changes Were Needed

EPA's performance under the New Chemicals Review Program prior to enactment of the LCSA justified this Congressional commitment to the status quo, except for relatively minor improvements. Prior to June 22, 2016, EPA received 50,592 new chemical notices, of which 40,151 were for PMNs.[5]

- Of those 40,151 PMNs, only 14,206 resulted in submission of a Notice of Commencement of Manufacture or Import (NOC), or about 35%. This means that a combination of EPA actions and commercial decisions by submitters in light of EPA actions and other considerations kept about 65% of all PMN substances from reaching the commercial marketplace.
- EPA issued 1,729 section 5(e) orders (for about 12% of all PMNS for which an NOC was submitted).
- Of those section 5(e) orders, 764 were followed by SNURs (about 44%).
- EPA also promulgated another 793 SNURs without issuing a section 5(e) order, for a total of 1,557 SNURs, almost all of which were for PMN substances. This means that about 17% of all PMNs for which an NOC was submitted became the subject of a SNUR.

These statistics mean that, prior to enactment of the LCSA, EPA's New Chemicals Review Program reviewed tens of thousands of PMNs relatively efficiently, handling about 1,000 PMNs per year. About 68% of the PMNs resulted in a section 5(e) order, a SNUR, or both, or a submitter's decision not to commercialize the substance. Notably, however, EPA was able to conclude that many PMN substances did not need to be restricted because they did not meet the "presents" or "may present" standard. EPA itself stated that section 5 as implemented pre-enactment was very effective at keeping unsafe new chemical substances off the market.[6]

3. The Changes to Section 5 Were Limited

The LCSA's changes to section 5 were relatively limited. They mainly relate to the affirmative finding requirement of section 5(g); the limitation of any risk determination to consideration of risks to health or the environment; and the limited inclusion of "conditions of use" in the risk calculus.

---

[5] These and other statistics in these comments are from EPA, Statistics for the New Chemicals Review Program under TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (last updated Jan. 11, 2018).

[6] See, e.g., EPA, Fiscal Year 2017, Justification of Appropriation (Feb. 2016), https://www.epa.gov/sites/production/files/2016-02/documents/fy17-congressional-justification.pdf, at 517 (consistently high marks on EPA's own metric, "Percent of new chemicals or organisms introduced into commerce that do not pose unreasonable risks to workers, consumers, or the environment").

a. The "Not Likely to Present" Affirmative Finding

First, section 5(g) now requires EPA to make an affirmative finding when it determines that a PMN substance is "not likely to present" an unreasonable risk and to publish that finding. Previously, EPA effectively made just such a finding when it determined that it would not make a "likely to present" finding in a section 5(e) order. (If a PMN substance is not "likely to present" an unreasonable risk, then logically it is "not likely to present" such a risk.) Previously, EPA did not have to explain the basis for its decision; now it does. EPA must "show its work" on new chemicals. The Senate Report observed:

> As with other provisions of S. 697, the section ensures transparency in all EPA decisions on new chemicals or significant new uses.[7]

In other words, the Senate Report considered that the requirement in the legislation for an affirmative finding would enhance transparency; it did not consider that a change in the substantive standard.

b. Risks to Health and the Environment Only

Second, the LCSA emphasized repeatedly that the scope of a risk determination, even under section 5, is to relate solely to health or environmental risks. Section 5(a)(3)(C) now provides that EPA may determine:

> that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, **without consideration of costs or other nonrisk factors**, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(Emphasis added.) However, since EPA had always focused primarily or exclusively on health or environmental risks, little change was required. Consideration of costs and other nonrisk factors had figured largely in the pre-enactment section 6 by its terms. Indeed, costs and nonrisk factors were decisive in the court decision on the section 6 asbestos ban. In contrast, such considerations had never been significant under section 5, since PMN chemicals by necessity are not yet in commercial distribution.[8] Thus, the result of the legislative change was to codify pre-enactment EPA practice rather than to change that practice.

---

[7] Senate Report at 14.

[8] In his Congressional testimony on TSCA legislation, then-Assistant Administrator Jim Jones lamented the requirement in section 6 to balance costs and benefits. In contrast, he had few, if any, criticisms of section 5 other than the absence of a need to articulate a "not likely to present" finding.

c. Conditions of Use

Third, section 5(a)(3)(c) requires that EPA make its "not likely to present" determinations in light of "the conditions of use." Section 3(4) defines that term to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Again, EPA had always considered those circumstances in making its PMN risk determinations, because EPA expected the PMN submitter to provide the information for EPA's review. The Senate Report emphasized that "reasonably anticipated" (a clear reference to "reasonably foreseen") exposures should be considered "consistent with existing law" and that the PMN submitter (who has no knowledge of the conditions of use of anyone besides itself and its direct customers) must submit the information on those exposures:

> Consistent with existing law, the PMN submitter must provide EPA all available relevant information, including information on the intended conditions of use and reasonably anticipated exposures. The Committee intends that the review of the PMN should be conducted in that context.[9]

It is clear from this statement that Congress expected that the current PMN regulations would govern the information that EPA is to consider in reviewing PMNs. Those regulations require a PMN submitter to provide exposure-related information both for sites controlled by the submitter and for sites not controlled by the submitter, including the "categories of use."[10] Yet EPA has never interpreted those long-standing regulations to require information about uses by other manufacturers of the PMN substance after it is added to the Inventory. In the LCSA, Congress considered that "reasonably anticipated exposures" would be those resulting from the activities described in the PMN. Congress did not require speculation about possible activities of future manufacturers and processors once the PMN substance was added to the Inventory.

So why did Congress include the term "conditions of use" in the LCSA? It did so primarily to affect EPA's risk decision making under section 6. There is no indication that it intended for that term to change EPA's decision making under section 5. The inclusion of "conditions of use" in section 5 was for the sake of consistency throughout the statute, rather than for the purpose of overhauling the scope of PMN reviews.

Under section 6, where many people may use a chemical substance, it may be appropriate to consider a broad range of reasonably foreseeable activities. The House bill, H.R. 2576, did not propose to amend section 5, and it used the term "intended conditions of use" only in the definition of that term and in its amendments to section 6. The Senate Report also focused only on use of the term in section 6:

---

[9] Senate Report at 15.
[10] 40 C.F.R. § 720.45(f)-(h).

> "Conditions of Use" is a term used throughout S. 697 to describe the context in which EPA will apply the safety standard in safety assessments and determinations. The term means the "intended, known, or reasonably foreseeable circumstances" under which a chemical substance is manufactured, processed, distributed in commerce, used or disposed of. The term is not intended to include "intentional misuse" of chemicals.[11]

The phrase "safety assessments and determinations" corresponds to the phrase "risk evaluations" in the final legislation. Thus, Congress saw the term as mainly affecting risk evaluations under section 6.[12] There is no evidence that it gave any consideration to how referring to "conditions of use" in section 5 might affect EPA's review of PMNs. Certainly, Congress expressed no intention to upend the New Chemicals Review Program by mandating a much more expansive scope to PMN reviews in light of the use of that term in section 5.

Indeed, Congress appears to have included "conditions of use" in section 5 haphazardly. For example, in section 5(a)(3)(B(ii)(I), the "may present" provision does not include the term, yet the parallel "may present" provision in section 5(e)(1)(A)(ii)(I) does include the term. This inconsistency suggests that inclusion of "conditions of use" in section 5 was an afterthought for the purpose of consistency throughout the amended statute and not a considered change intended to alter the scope of a risk determination for a PMN substance.

Notably, Congress also did not change EPA's discretion to reach uses beyond those identified by the PMN submitter. EPA still has ample section 5 authority to apply SNURs to new uses identified by manufacturers or processors.

II. EPA's Implementation of Section 5 Since Enactment Does Not Meet Section 5 Requirements

A. EPA Is Not Meeting Statutory Deadlines

Since June 22, 2016, EPA has made progress clearing the "backlog" of pending PMNs.[13] The agency is not, however, consistently meeting the 90-day requirement established by three separate subsections in section 5. These delays underscore industry's continuing concerns that the section 5 program remains too slow – and is not predictable. It is clear that Congress

---

[11] Senate Report at 7.

[12] See also Cong. Rec. S3519 (June 7, 2016) (remarks of Sen. Vitter responding to a question on how "conditions of use" should be applied by EPA in risk evaluations under section 6).

[13] EPA's statistics suggest that since a "low" during August/September of 2017, the backlog has actually been creeping up again, with 453 pending cases as of January 9, 2017. As noted later in these comments, EPA is typically only able to meet the 90-day deadline through liberal use of "voluntary" suspensions. EPA also routinely "suspends" action on Low Volume Exemption (LVE) submissions. As we recommend in these comments, EPA should develop new, clearer metrics for performance under the New Chemicals Program. For example, the endpoint used to judge clearing the "backlog" created after LCSA enactment was the decision to issue a consent order – a point in time that exceeded the statutory review period. Even after the decision to issue a consent order, the PMN submitter is typically many months away from a final consent order and an ability to submit a NOC.

intended to preserve the function of the New Chemicals Program with added transparency; it did not intend to add complexity, uncertainty, and delays.

Our concerns with widespread delays in reaching decisions extend to EPA's consideration of a non-order SNUR where the PMN review period would remain open until the SNUR is published. Historically, EPA has not begun work on a SNUR until after finalizing the section 5(e) order for the PMN substance. The use of a non-order SNUR would likely substantially delay a PMN submitter's ability to commence manufacture of its PMN substance (unless EPA adopts our recommendations, set out separately, to accelerate publication of the SNUR).

An analysis of the data from the SNUR and PMN tables[14] is illustrative of the problem:

Section 5(f)(4) requires EPA to consider whether or not to issue a SNUR for substances that may present, or present, an unreasonable risk, within 90 days following the 5(e) or (f) order. There is no statutory requirement that a SNUR of any kind (including a "non-order SNUR") be issued contemporaneous to the order or "not likely" statement.

- Prior to LCSA Enactment: In the 12 months prior to June 22, 2016, EPA issued direct final SNURs an average of 395 days after the effective date of the 5(e) order [range was 177 to 1060 days].
- Post LCSA Enactment: EPA averaged 364 days to issue a SNUR after the effective date of a 5(e) order [range was 12 to 734 days].
- PMN Submitted after Enactment: Even for PMNs submitted after enactment, EPA took an average 255.5 days to issue a SNUR [range was 226 to 271 days]. In the last 90 days before the December public meeting alone, the average was 322 days.
- Even in the last 90 days before the December public meeting, EPA has issued direct final SNURs for PMN substances that are subject to a section 5(e) order an average of 322.5 days after the effective date of the section 5(e) order [range during that period was 160 days to 734 days].

Section 5(e)(1)(A) as amended directs EPA to issue section 5(e) orders that take effect at the end of the 90-day review period for PMNs (subject to certain exceptions, which are rarely applicable).

- Prior to Enactment: In the 12 months prior to June 22, 2016, EPA issued section 5(e) orders with effective dates that average 694 days after the date EPA received the PMN [range was 91days to 1561 days].
- Post Enactment: Since June 22, 2016, EPA has issued section 5(e) orders with effective dates that average 406 days after the date EPA received the PMN for the chemical substance [range was 98 days to 1545 days].

[14] Note that these figures address only chemicals substances that are subject to a proposed or final SNUR; they do not capture all chemical substances that are subject to a section 5(e) order. We have appended three Excel spreadsheets to these comments providing the data from which the analysis was drawn.

- PMNs Submitted after Enactment: Even for PMNs submitted after enactment, it is an average of 208 days following submission of a PMN to the effective dates of section 5(e) orders [range was 98 days to 258 days].

The average number of days to a consent order does not convey a complete picture, however. Out of 250 total entries for 5(e) consent orders, 158 have no information regarding the timing of the consent order. On the basis of the remaining 92 entries that included consent orders, however, the data show that the vast majority of those orders were issued well beyond 180 days after submission of the PMN:

Number of Days to 5(e) Order from Submission of PMN	**Absolute Numbers**	**Percentage**
90 days or less	0/92	0%
>90 days but <180 days	19/92	21%
Total 180 days or less	19/92	21%
>180 days	73/92	79%

Section 5(g) clearly contemplates that EPA will make its "not likely to present an unreasonable risk" determinations in less than 90 days after submission of the PMN. It provides that once EPA makes a "not likely to present" determination, then the PMN submitter may commence manufacture "notwithstanding any remaining portion of the [usually 90-day] review period." In practice, however, EPA has typically taken longer than 90 days to make a "not likely to present" determination, even though such determinations presumably are made for PMN substances presenting little risk.

- Post Enactment: During the first 17 months since enactment of the LCSA, EPA announced 63 "not likely to present" determinations.
- The "not likely to present" determinations took an average of 115.5 days from the date EPA began review of the PMN until the date EPA made the determination (this includes PMNs that were submitted prior to enactment)[range was 35 days to 404 days].
- PMNs Submitted after Enactment: For PMNs that were submitted after enactment, the "not likely to present" determinations took an average of 116.5 days from the date EPA received the PMN until the date EPA made the determination [range was 31 days to 371 days].
- EPA has only announced 16 "not likely to present" determinations for PMN substances that were submitted after January 1, 2017. These determinations took an average of 83.5 days from the date EPA received the PMN until the date EPA made the determination [range was 31 days to 168 days].
- This category of delays create concern that EPA is simply taking too much time to make "not likely to present" determinations. EPA should be able to make such determinations

in many cases after the Focus Meeting (approximately 20 days after submission and receipt of the PMN), at which time EPA typically decides whether or not to initiate standard review for the PMN substance.

As above, information on the average amount of time to a determination does not convey the complete picture. Of 63 total entries, information was not available on 4, so the percentages reflected below are calculated on the basis of 59 entries.

Number of Days to Not Likely Determination From Date PMN	Absolute Numbers	Percentage
90 days or less	32/59	54%
>90 days but <180 days	16/59	27%
Total 180 days or less	48/59	81%
>180 days	11/59	19%

As these statistics indicate, EPA clearly has difficulty meeting the statutory review deadline. There are of course a number of reasons for this: information not provided by submitters, the "ping-pong" in communications between EPA and submitters, EPA's frequent requests for extensions or suspensions (where there is no alternative for the submitter except to withdraw the PMN), and delays caused by re-assessments upon the receipt of new information or re-runs of engineering reports, among others. None of this is what Congress had in mind when it amended TSCA. Had Congress intended to extend the review period, it could have; but instead it further reinforced EPA's obligation to meet the review period by requiring the agency to refund fees if the timeline is not met.

As these comments note, Congress' key concern with Section 5 was improved transparency. EPA's performance in the months following statutory amendment point to a significant need for better metrics in the section 5 program. We suggest the agency do the following:

- Segregate and track PMNs separately from Microbial Commercial Activity Notices (MCANs) and SNUNs. While the "total cases" figures offered by EPA are helpful, it would be considerably more helpful to have each type of submission separately represented.
- Make public the number of extensions for specific PMN submissions, and the general reason for the extension request. Tracking this metric will provide a better view of whether EPA is making progress to eliminate unnecessary delays in the system.
- Ensure that the effective date of a section 5(e) order is made public for all relevant PMNs. Some information is simply not currently available and therefore the entire universe of section 5(e) orders during the relevant time periods could not be assessed.
- Likewise, track the initial publication date and effective (final) date of any SNURs.

- EPA should also consider issuing performance goals for sections 5(f)(4), section 5(e) and 5(g) actions. Those goals would provide a useful way of benchmarking EPA's effort to meet the 90 (or 180) day deadlines, as established by Congress.

The analysis of PMN decision making and enhanced EPA transparency are clearly needed in order to address the misperceptions of some stakeholders, particularly those who have never invested substantial resources in developing new chemicals or who have never filed a PMN. ACC believes it is incumbent on EPA to publicly address the erroneous or misleading statements of some stakeholders. Some of those statements greatly exaggerate the implications of EPA's PMN review process. Others ignore both the law and practice of new chemical reviews.

For example, EPA has given no indication that it intends to forgo consent orders entirely, and especially not in cases where they have concerns or insufficient information about the PMN submitter's intended use. The "non-order SNUR" is essentially the same as a "non-5(e) SNUR," which was used when EPA had no reason to regulate a PMN submitter's intended use but wanted to protect against reasonably foreseen uses by other companies.

Some contend that consent orders must be "posted visibly within any workplace where activities subject to the consent order are taking place," in contrast to the conditions of a SNUR. ACC is not aware of any requirement that a consent order "be posted visibly within any workplace" – some consent orders may require a copy of the order to be kept at manufacture or processing sites, but there are no additional posting requirements. More to the point, SNURs are no less enforceable than consent orders. Each SNUR has specific recordkeeping requirements that ensure that companies must demonstrate that they have not engaged in a "new use." For both consent orders and SNURs, the only way EPA can "know" that a company is abiding by the conditions is to actually inspect them. EPA can identify manufacturers and importers of SNUR substances through CDR reporting, and can target them for inspections accordingly.

Other commenters have noted that testing requirements cannot be imposed through a SNUR, ignoring that SNURs commonly contained recommended tests that SNUN submitters are expected to submit in the cases where they would like to engage in a "new use."[15] If they fail to do so, EPA can compel the testing during the SNUN review process. EPA can therefore require testing through careful definition of "new uses."

The point is that EPA must not only be transparent with its decisions under section 5, it must take steps to address misconceptions and errors suggested by others that implicate the integrity of the program. One of the clear objectives of the LCSA was to enhance public confidence in decisions on chemicals; that confidence can only be built on a transparent activity and the Agency's willingness to defend its actions.

---

[15] See, e.g., Significant New Use Rules for Certain Chemicals, 82 Fed. Reg. 44079 (Sept. 21, 2017)(for certain PMNs submitted before June 22, 2016). Since then, it appears that three SNURs have been issued for PMNs received after June 22, 2016 that contain testing recommendations (cases P-16-455; P-16-503; and P-16-591).

B. EPA's "May Present" Decision Making Does Not Meet Section 5 Criteria

Before the Lautenberg amendments to TSCA, to support a Section 5(e) order in the face of insufficient information to support a reasoned evaluation, EPA needed to determine that the substance "may present" a substantial risk of injury to health or the environment (or that there will or may be substantial human or environmental exposure to the substance). Congress did not change the decision criteria; it added requirements for transparency, and in particular, documentation of the rationale that formerly would have accompanied "dropped" PMNs – PMNs now achieving "not likely to present" determinations. Accordingly, implementation of the amended statute should show roughly the same number of PMNs with Section 5(e) consent orders now associated with "may present" determinations, and roughly the same ratio of formerly "dropped" PMNs now associated with "not likely to present" determinations.

The data, however, does not bear this out. As discussed above at I.B.2, EPA issued 1,729 section 5(e) orders pre-amendment, or about 12% of all PMNs for which a NOC was submitted. Post amendment (as of January 9, 2018), EPA notes 302 cases associated Section 5(e) orders; 154 cases withdrawn, and 116 cases of "not likely to present" with only 419 NOCs received. At this phase of implementation, EPA's ratio of "may present" determinations has radically shifted with no underlying change in the substantive elements of risk-based review and no change in the statutory meaning of "may present." It is not reasonable to expect that all or most "insufficient information" cases that previously would have been dropped are suddenly now determined to be "may present" cases – in fact, it may be the case that the "withdrawn cases" category represents the majority of insufficient information cases.

III. EPA Should Adopt Process Improvements to the New Chemicals Review Program

EPA has already taken steps to improve the PMN review process and provide additional guidance to aid PMN submitters. This section provides specific recommendations for EPA to streamline the PMN review process, improve the order negotiation process, and increase transparency in the New Chemicals Review Program.

A. EPA Should Take Steps to Maximize the Effectiveness of Pre-Notice Consultations

EPA should maximize the usefulness of Pre-Notice Consultation meetings. The November 6, 2017 draft *Points to Consider When Preparing TSCA New Chemical Notifications* document provides some useful guidance to help PMN submitters prepare for a Pre-Notice Consultation. However, EPA should provide additional guidance regarding the Pre-Notice Consultation process to ensure that PMN submitters send useful information to EPA prior to the consultation, and come prepared to ask the right questions.

That process presents an opportunity for the PMN submitter and EPA to have an open discussion prior to submission of a PMN. According to the draft *Points to Consider*, EPA will provide a summary of the Pre-Notice Consultation meeting from the PMN submitter that includes a set of minutes, any commitments made by EPA or the submitter and any conclusions reached at the

meeting.[16] EPA should also agree to offer the PMN submitter specific recommendations after the consultation, such as what additional information the PMN submitter should consider including in its PMN.

EPA has appropriately indicated that it will not make any determinations at a Pre-Notice Consultation meeting regarding whether there may or may not be potentials risks to human health or the environment.[17] EPA could, however, still provide useful feedback to the PMN submitter regarding potential issues based on analogues to the chemical substance, if available, or information relevant to the broader chemical class in which the substance falls into.

EPA could also consider and provide feedback regarding the level of information available on the chemical substance. This would allow the PMN submitter to consider whether to develop additional data or attempt to identify other information to fill in any perceived data gaps prior to submitting a PMN.

Finally, EPA could also provide feedback regarding the proposed and reasonably foreseeable conditions of use. EPA could recommend that the PMN submitter offer additional details regarding its proposed uses.

B. EPA Should Streamline the PMN Review Process

EPA should adopt changes to the PMN review process to increase its efficiency and improve communication between EPA staff and PMN submitters throughout the process.

1. EPA Should Conduct Its Initial Reviews in Parallel

Rather than conducting initial reviews in a serial manner, EPA should conduct parallel reviews to expedite the process. EPA is already conducting some of its initial reviews in parallel, but should continue to look for opportunities for process improvements. For example, EPA should undertake the initial chemistry review, TSCA Inventory status review, human and ecological hazard identification, and evaluation of the conditions of use in parallel after a PMN has been submitted.

EPA should also consider developing exposure and release profiles while conducting these initial reviews, instead of waiting for the results of the Structure Activity Team meeting.

The process could also be improved by holding the Chemical Review & Search Strategy (CRSS) and Structure Activity Team meetings in tandem, instead of conducting these meetings in a series. In addition to these suggestions, EPA should look for additional opportunities to revamp the PMN review process.

---

[16] Draft *Points to Consider When Preparing TSCA New Chemical Notifications* (Nov. 6, 2017), at 9.
[17] *Id.* at 8.

2. EPA Should Provide the Results of Its Initial Evaluations to the PMN Submitter

EPA should provide the results of its initial evaluations to the PMN submitter after the Focus Meeting to ensure the PMN submitter understands any potential concerns early in the process.

By default, EPA should provide the following information to the PMN submitter, even if in draft form:

- The conditions of use being evaluated by EPA
- SAT Report
- Engineering report
- Exposure assessment
- A summary of EPA's preliminary assessment of the human health and/or environmental risks

EPA relies on these evaluations as a basis for its decision making. Disclosing them would help the PMN submitter understand any particular areas of focus and potential concerns so that it may more quickly address those concerns.

3. EPA Should Consult with the PMN Submitter After the Focus Meeting

Another practical option available to EPA is to discuss its initial concerns with the PMN submitter immediately after the Focus Meeting, which is usually held 15 to 20 days after the submission of a PMN.

In the discussion, EPA should explain its preliminary conclusions from the Focus Meeting to the PMN submitter. This could include a review of EPA's initial evaluations, such as of the SAT Report, engineering report, exposure assessment, etc., and any potential concerns. This may allow the PMN submitter to respond to questions underlying those initial concerns; to correct misimpressions; and to offer information or changes to exposure controls which may effectively resolve those initial concerns. This discussion may address EPA's concerns and identify paths to avoid the need for a section 5(e) order.

The discussion could identify information that would help EPA resolve its concerns. For example, the PMN submitter may not have recognized that EPA may regard "disposal" of wastes to include disposal in a municipal waste landfill, whereas the PMN submitter had planned to dispose of the PMN substance as hazardous waste. Alternatively, the PMN submitter could offer to amend its proposed waste treatment process in the PMN to address EPA's concerns.

This is particularly useful where EPA may be considering a section 5(e) order based on "insufficient information." While PMN submitters are required to submit all available health and safety studies, a concern about hydrolysis, for example, may trigger a more detailed search that uncovers an existing hydrolysis study (e.g., as submitted to a foreign regulatory body). Alternatively, the PMN submitter may decide to conduct a hydrolysis study.

The PMN submitter may be able to refer EPA to previous evaluations of the PMN substance by EPA's foreign counterparts, e.g., in China or in the European Union under REACH.[18] Although those evaluations would not be binding on EPA, they may prove useful and inform EPA's evaluation.

4. EPA Should Take Steps to Eliminate the "Ping-Pong" That Occurs During the Standard Review Process

In addition to meeting with the PMN submitter after Standard Review, EPA should provide as complete a set of questions and additional information needs to the PMN submitter as soon as possible upon initiating Standard Review. This would allow the PMN submitter to provide additional information to EPA earlier in the process and help avoid the "ping-pong" – the back-and-forth between EPA and submitters – that often occurs with the introduction of new information during Standard Review.

One aspect of the Review Process may in fact encourage the "ping-pong." Based on current practice, it is apparent that different elements of the EPA process may not have access to key details of the review, such as the details of a pollution prevention assessment. Ensuring that all PMN information is available to all EPA reviewers would also help minimize the opportunities for "ping-pong-ing" between EPA and submitters.

The current PMN Review Process has been burdened by significant delays as a result of multiple requests for information from EPA during Standard Review, and the submission of additional information on a piecemeal basis by PMN submitters. Under the current process, PMN submitters may continue to answer series of questions and submit multiple rounds of follow-up information in response to periodic requests from EPA. The introduction of new information can alter EPA's conclusions, requiring it to reexamine the hazards of the chemical substance, rerun engineering reports or exposure assessments, or reevaluate the human health and environmental risk assessments.

This back-and-forth even occurs during the negotiation of a section 5(e) order. A PMN submitter may not be aware of a particular concern until it arises in the context of a proposed order. Upon learning of a concern, the submitter may be compelled to provide additional information to address a concern raised in the order. This can result in a reexamination of the underlying risk assessment and further delay in finalizing the order. Understanding those concerns earlier in the process before a section 5(e) order is even contemplated would reduce the changes of this scenario. It could even obviate the need for a section 5(e) order in the first place if the submitter amends its PMN to respond to such concerns.

Clearly, both EPA and the PMN submitter are responsible, in part, for the back-and-forth that occurs during the Standard Review process. But EPA can take steps to reduce, and in some

[18] ACC believes that EPA should routinely evaluate Robust Study Summaries (RSS) available under Europe's REACH program. Although RSS may not be sufficient as a basis for a final determination on a substance, they are likely to indicate the availability of information relevant to decisions under TSCA.

cases even eliminate it . Therefore, EPA should prepare as complete a set of questions and additional information needs for the PMN submitter immediately upon initiating Standard Review.

C. EPA Should Improve the Section 5 Order Negotiation Process

The increase in section 5(e) orders has also contributed to avoidable delays in the PMN review process. The time needed to develop, negotiate, and issue a section 5(e) order can push back the completion of the PMN review period by months. EPA should consider building a formal process to begin discussing the proposed terms of an order with the PMN submitter before it is finalized.

After EPA determines that a section 5(e) order is necessary, it initiates an extensive internal process. The order provisions are developed, undergo legal review, and are finalized by EPA with little or no discussion with the PMN submitter. The order is then signed by an EPA official and issued to the PMN submitter. This is usually the first time the PMN submitter has seen the terms of the order or had the opportunity to review them. Unless the PMN submitter accepts the terms of the order outright, it must submit a request to modify the terms. Depending on the request, EPA may require that the PMN submitter provide additional information to support its request (which can lead to the recycling discussed in the previous section). Any request to modify a substantive provision of an order triggers another round of internal review within EPA to approve such request. This again results in further delays.

EPA should communicate with the PMN submitter upon determining that an order is necessary, and share the nature of EPA's concerns and any potential requirements being considered for inclusion in an order. Communicating these concerns and any potential requirements early in the process would allow the PMN submitter to evaluate the requirements and begin discussions with EPA sooner.

This is especially important if EPA intends to include a provision in the order that would bind downstream manufacturers or processors of the PMN substance to certain requirements. A PMN submitter may not be able to negotiate the terms of an order without considering the potential impacts of the order on its downstream supply chain, and consulting with its customers.

D. EPA Should Increase Transparency in the New Chemicals Review Program

Greater transparency by EPA in the PMN review process is critical to ensure that current and future PMN submitters and other stakeholders understand EPA's decision making under TSCA, as intended by Congress.

The new affirmative determination and public notice requirements serve as a mechanism for transparency about the decisions that EPA makes regarding new chemical substances. Additional transparency will give stakeholders other than the PMN submitter insight into EPA's actions and the reasons for those actions. Stakeholders who question those actions will have several opportunities to raise objections, including through comments on a proposed SNUR for the PMN substance; requesting EPA to identify the PMN substance as a high-priority substance

under section 6; and filing a section 21 petition or a petition under the Administrative Procedure Act asking EPA to undertake specified activities.

Pre-enactment, whenever EPA decided not to regulate a PMN substance, it offered no explanation for its decision – it simply took no action. In contrast, where EPA did issue a section 5(e) order, it provided an explanation of its decision in the order itself, with the order being available to the PMN submitter and to the public through FOIA, subject to section 14 protections on confidential business information.

Section 5(a)(3)(C) mandates that EPA make an affirmative determination about each PMN found to be "not likely to present an unreasonable risk." Under new section 5(g), EPA must publish in the Federal Register a summary of each determination that a PMN substance is "not likely to present an unreasonable risk," thus providing greater transparency regarding those determinations. The purpose of transparency is to allow the public to understand and, at times, question EPA's decisions.

Another benefit of greater transparency is increasing the understanding of EPA's new chemicals review program. If more detailed information is released explaining EPA's unreasonable risk determinations for PMNs, future PMN submitters will be able to better understand the decision making process and better anticipate and respond to potential concerns.

E. EPA Should Expand the Sustainable Futures Program

The Sustainable Futures Program, https://www.epa.gov/sustainable-futures, has continued to serve as a valuable program for PMN submitters and EPA. EPA should continue to support Sustainable Futures and expand its use of the Program moving forward as another option to streamline the PMN review process for companies that choose to operate under the Sustainable Futures Program.

To date, Sustainable Futures has served as a valuable resource for PMN submitters that are involved in the program and EPA by:

- Helping manufacturers to incorporate pollution prevention principles in the development of new chemical substances using established hazard, exposure, and risk screening methodologies, and avoid the commercialization of chemicals with less preferable human health or environmental profiles.
- Encouraging manufacturers to consider testing, where appropriate, to develop data that will inform the PMN review process and overcome default assumptions.
- Helping PMN submitters consider what potential exposure controls or limits on releases might be appropriate for a new chemical based on its risk profile.
- Providing further guidance and insight into the PMN review process for PMN submitters, and helping PMN submitters prepare complete and accurate PMN submissions.
- Providing useful information to EPA in the initial PMN submission that informs the PMN review and evaluation of PMN substances.
- Expediting the review timeline for PMNs submitted as Sustainable Futures submissions.

EPA should continue to support the Sustainable Futures Program so that both PMN submitters and the Agency may continue to reap these benefits.

EPA should also reaffirm its commitment to accepting and considering data from PMN submitters generated through the Sustainable Futures framework. In some instances, EPA has afforded little weight to information provided by PMN submitters that was generated through Sustainable Futures. This undermines confidence in the Sustainable Futures Program and defeats one of its primary purposes – to develop better information to inform the PMN review process. PMN submitters will have less incentive to use the Sustainable Futures Program and generate information if the information they provide from that Program is ignored by EPA.

The option of using the Sustainable Futures Program to expedite the PMN review process is now more important than ever, given that EPA is still struggling to meet its statutory deadlines. The Sustainable Futures Program is another resource that EPA can promote to PMN submitters to accelerate its review of a PMN and avoid many of the delays in the process. It is unclear whether the Sustainable Futures program has actually been used since enactment of the LCSA; it would be unfortunate if this were the case.

EPA should expand and further promote the Sustainable Futures Program. In that regard it should continue to provide incentives for PMN submitters to utilize that Program.

IV. EPA May Issue Non-Order SNURs But Should Improve the Process for Doing So

EPA has indicated that it plans to issue a "non-order SNUR" where the activities described in a PMN allow it to make a "not likely to present" finding with respect to those activities but it has concerns about possible activities of future manufacturers and processors after the PMN substance is added to the Inventory. This situation would arise where EPA finds that the PMN substance has or may have health or environmental hazards. That would raise the question of whether exposure controls will be sufficient for EPA to make a "not likely to present" risk finding (risk being a function of hazard and exposure), or instead may be insufficient such that it must make a "likely to present" risk finding and issue a section 5(e) order. Where the exposure controls in the PMN, or an amended PMN, appear to be sufficient, EPA plans to make a "not likely to present" finding and to promulgate a SNUR to ensure that the exposure controls used by future manufacturers and processors are also sufficient.

Contrary to the assertion of some stakeholders, EPA has not suggested that non-order SNURs replace section 5(e) consent orders. Indeed, there appears to be significant confusion among some commenters about non-order SNURs, although they are the logical replacement for non-section 5(e) SNURs following the enactment of LCSA. Stakeholders have raised several other objections to this approach:

1. EPA's perceived need for a SNUR somehow implies that the PMN substance "may present" an unreasonable risk, thus precluding a "not likely to present" finding.
2. EPA must make a "may present" determination for the PMN substance because the exposure controls described in the PMN are "voluntary" and must be made enforceable through a section 5(e) order.

3. A SNUR is not an effective means of enforcing use of exposure controls.
4. Possible actions of future manufacturers and processors of the PMN substance preclude EPA from making a "not likely to present" finding.

As discussed below, these objections do not hold up to scrutiny, either with respect to the activities of the PMN submitter or with respect to possible activities of future manufacturers and processors.

Although EPA has authority to issue non-order SNURs, it should revise the planned process for doing so by making the "not likely to present" finding first and then promulgating the SNUR. It should not delay issuing the "not likely" finding until the SNUR becomes effective. EPA should begin work on the SNUR during the PMN review period and promulgate it within a few months after the review period ends.

A. EPA Has Promulgated SNURs Without Issuing Section 5(e) Orders for Decades

EPA should assess arguments against a non-order SNUR in light of its decades of experience with promulgating SNURs without first issuing a section 5(e) order.

EPA has a regulation authorizing it to promulgate SNURs without first issuing section 5(e) orders, 40 C.F.R. § 721.170. EPA adopted this expedited process for promulgating non-section 5(e) SNURs because "a non-section 5(e) SNUR may be the least burdensome regulatory alternative for the Agency to pursue." In doing so, it advanced the policy of section 2(b)(3), that:

> authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

As explained in the 1995 preamble adopting that regulation:

> A non-section 5(e) SNUR is typically appropriate for PMNs on chemical substances expected to be toxic but where the PMN indicates the submitter's intention to limit activities, implement control measures, or otherwise adequately mitigate human exposures and environmental releases. **Activities described in such PMNs may not present an unreasonable risk of injury** to human health or the environment so as to warrant the issuance of an Order under section 5(e) of TSCA, but deviations from the described activities may present an unreasonable risk warranting the imposition of regulatory controls via a section 5(e) Order. In those cases, **a non-section 5(e) SNUR may be the least burdensome regulatory alternative** for the Agency to pursue, as it will allow the PMN submitter to proceed with planned activities while requiring notification to, and review by, EPA for activities which have not been reviewed.[19]

[19] 60 Fed. Reg. 16311, 16313 (Mar. 29, 1995) (emphasis added).

EPA concluded that the use of non-section 5(e) SNURs would "eliminate unnecessary section 5(e) Orders" then being issued to PMN submitters:

> Thus, this rule amendment is intended to eliminate unnecessary section 5(e) Orders and should not itself increase the number of new chemical substances regulated by EPA via SNURs under section 5 of TSCA. Rather, substances that would formerly have been regulated by 5(e)-SNURs may now be regulated by non-section 5(e) SNURs.[20]

Unnecessary section 5(e) orders hurt all parties. EPA is burdened with the additional work of drafting, negotiating, and adopting those unnecessary orders. PMN submitters are burdened by the delay of waiting for EPA to draft the orders, negotiating them with EPA, and then waiting for EPA to issue the orders. The public and the environment are burdened from the same delay, as innovative technology and greener chemicals are kept from the market for sometimes extended periods.

As noted above, in the period prior to enactment of the LCSA, EPA promulgated 793 SNURs without first issuing a section 5(e) order. That number represents over half of all SNURs promulgated during that time. In each of those cases, EPA found that the exposure controls described in the PMN were sufficient to permit it not to make a "may present" determination.

That logic and experience apply today as well, despite the amendments to TSCA, as discussed below.

B. A SNUR Does Not Imply That a Chemical Substance "May Present" an Unreasonable Risk

The logic of some stakeholders appears to be that the need for a SNUR precludes a "not likely to present" finding and mandates a "may present" determination. That logic misconstrues what a SNUR is.

Section 721.170(a) explains the idea behind promulgating a SNUR without first issuing a section 5(e) order:

> EPA may issue significant new use notification and recordkeeping requirements for any new chemical substance for which a premanufacture notice has been submitted under part 720 of this chapter if EPA determines that activities other than those described in the premanufacture notice may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects.

In the non-order SNUR context, EPA is prepared to make a "not likely to present" finding with respect to activities described in the PMN. A SNUR would apply to the PMN submitter, but, more significantly, it would also apply to future manufacturers and processors whose possible

[20] 60 Fed. Reg. at 16313.

activities "may result in significant changes in human exposure or environmental release levels" from those described in the PMN.

The criteria for promulgating a SNUR do not include the likelihood of an unreasonable risk. Section 5(a)(2) requires EPA to consider "all relevant factors" before deciding to adopt a SNUR, but the likelihood of an unreasonable risk is not one of them. Instead, to promulgate a SNUR, EPA must simply consider the relevant factors and find that a use is both "new" (i.e., not ongoing) and "significant." The legislative history sets a low standard for what EPA may regard as "significant":

> Thus, the conferees intend that any potential threats to health or the environment from the manufacture, processing, distribution in commerce, or disposal of a substance associated with a new use be considered by the Administrator when determining the significance of a new use.[21]

The standard, then, is one of "potential threats to health or the environment" – this is a far cry from a determination about unreasonable risk. That makes sense, since the function of a SNUR is to require a manufacturer or processor to submit a significant new use notice (SNUN) – effectively, a PMN – before commencing a significant new use so that EPA may determine whether the significant new use "may present" an unreasonable risk or meet the other criteria for restriction under section 5(e) or section 5(f). EPA must make exactly the same determinations under section 5(a)(3) following review of a SNUN as it must make following review of a PMN The SNUR itself acts as a regulatory mechanism to enable EPA to receive and review a SNUN, not a judgment by EPA that a chemical substance "may present" an unreasonable risk.

Significantly, the legislative history contemplated that EPA would promulgate SNURs on the basis of activities not described in a PMN:

> Thus, a significant increase in the projected volume of manufacture or processing for a substance, a significant change in the type or form of human or environmental exposure, or a significant increase in the magnitude or duration of human or environmental exposure could be the basis for determining that a use is a significant new use.[22]

The emphasis here is on increased or different exposure to a chemical substance. In the context of a PMN substance being considered for a SNUR (by far the most common context for SNURs), this means that Congress intended a SNUR to address, in the words of 40 C.F.R. § 721.170(a), "activities other than those described in the premanufacture notice [that] may result in significant changes in human exposure or environmental release levels" from those resulting from the activities described in the PMN.

In other words, Congress expected that many SNURs would be based not on activities identified in the PMN and those reasonably foreseeable from them, but rather on activities not identified in

---

[21] H. R. Rep. No. 94-1679 (Sept. 23, 1976) at 66, reprinted in Legislative History of the Toxic Substances Control Act (1976) at 679.
[22] Id.

the PMN – i.e., those of other manufacturers and processors after the PMN substance is added to the Inventory. Yet Congress did not make issuance of a section 5(e) order or action under section 5(f) a prerequisite for a SNUR. Accordingly, EPA remains free to find that the activities of a PMN submitter are "not likely to present" an unreasonable risk.

C. The Exposure Controls in a PMN or Amended PMN Are Not "Voluntary"

Some stakeholders have objected that EPA cannot issue a "not likely to present" finding in the context of a non-order SNUR because the exposure controls in the PMN are unenforceable without a section 5(e) order. They particularly decry EPA allowing a PMN submitter to amend its PMN to include additional exposure controls, with EPA then making "not likely to present" finding based on the amended PMN. These stakeholders argue that the exposure controls described in a PMN or amended PMN are "voluntary" and not enforceable and, as a result, EPA must make a "may present" determination.

This argument falls short, however. In every situation where EPA has hazard concerns about a PMN substance, potential exposure is the critical factor in the risk determination. The objections based on the "voluntary" nature of the controls is that EPA must issue a section 5(e) order or take action under section 5(f) in every case where EPA has any hazard concerns about a PMN substance, in order to ensure that the exposure controls in the PMN are enforceable. That has never been a requirement of the statute (before or after LCSA), EPA's practice, and it is not warranted.

Moreover, the exposure controls identified in a PMN (whether in the original PMN or in an amendment) are not "voluntary" in a meaningful sense. Every PMN includes a certification by an Authorized Official that, "to the best of my knowledge and belief ..., [a]ll information provided in this notice is complete and truthful as of the date of submission." Next to the signature block for the Authorized Official making this certification appears the following caution:

> The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

Thus, the PMN submitter must genuinely intend to use the exposure controls described in the PMN or else be subject to criminal penalties.

As a matter of administrative practice, EPA could ask a PMN submitter to check the "binding option" for the exposure controls in an amended PMN, to further confirm the submitter's commitment to use those controls. Historically, EPA has regarded the "binding option" as a gateway to a section 5(e) order, but there is no reason why it cannot be considered a commitment verified by the certification in the PMN even without a section 5(e) order.

PMN submitters are often reluctant to select the "binding option" because of concern that in the future alternative controls may become available that provide equal or greater protection to

health and the environment, yet they would be unable to make changes to controls for which "binding option" was selected. EPA could facilitate selection of "binding option" by revising the PMN Manual to explain that a "binding option" is a commitment of the PMN submitter for which it may be held accountable, and to indicate that if, after commercialization, the PMN submitter would prefer to change controls, it may simply send EPA a letter explaining the basis for the change and requesting EPA's approval. EPA could respond by letter approving the change, disapproving it, or suggesting alternative approaches. In this way, the "binding option" process could be made more effective and could be a much more efficient approach than requiring a section 5(e) order. EPA's SNUR regulations at 40 C.F.R. §721.30 already contain a process for EPA review and approval of alternative exposure control methods.

Finally, it should be noted that the objecting stakeholders are making only theoretical arguments. They have pointed to no actual instances of PMN submitters not utilizing the exposure controls described in their PMNs.

D. A Non-Order SNUR Would Be Effective in Enforcing the Use of Exposure Controls

Some stakeholders object, without evidence, that a non-order SNUR would be ineffective in requiring the use of exposure controls considered by EPA to be necessary, thus precluding EPA from making a "not likely to present" finding.

SNURS have proven to be extremely effective in keeping manufacturers and processors from engaging in the significant new uses identified in those SNURs except in the handful of instances where EPA has approved their doing so. A SNUR prohibits any manufacturer or processor from engaging in a designated significant new use without submitting a SNUN to EPA at least 90 days in advance (essentially triggering the New Chemicals Review Program for SNUR chemicals). During the 35 years of the New Chemicals Review Program prior to enactment of the LCSA, EPA received only 56 SNUNs (meaning, on average, fewer than 4% of the 1,557 SNURs became the subject of a SNUN). In practice, manufacturers and processors either avoided SNUR chemicals altogether, or else they ensured that they did not engage in the designated significant new uses, obviating the need for a SNUN.

The stakeholders may worry that the PMN submitter would not be bound to use the exposure controls described in the PMN after the end of the review period and before EPA could subsequently make a SNUR effective. This should not be a concern. The certification made in the PMN effectively addresses that period. If, shortly after the end of the PMN review period the PMN submitter were to drop any exposure controls described in the PMN, that would raise serious questions about whether the submitter violated the federal criminal code in making its certification.

The stakeholders or EPA may also worry that future manufacturers and processors would not be bound to use the exposure controls described in the PMN after the end of the review period and before EPA could subsequently make a SNUR effective. This should not be a concern either.

Over the 35 years prior to enactment of the LCSA, while it promulgated 1,557 SNURs, ACC is

aware of no instance where anyone other than the PMN submitter had begun manufacture of a PMN substance in such a manner that a use of concern to EPA had become an "ongoing use," meaning that EPA was precluded from issuing a significant "new" use rule for that use. This has been the case even where years have passed before EPA promulgated the SNUR. In the context of a non-order SNUR, EPA should plan to promulgate the SNUR as soon as possible after making a "not likely to present" determination, making the likelihood of another manufacturer commencing manufacture mostly theoretical.

An additional practical consideration is that most NOCs claim the identity of a commenced PMN substance confidential. This means that another manufacturer would not know that the particular PMN substance had been added to the Inventory. Even if a prospective manufacturer were to submit a bona fide notice of intent to manufacture under 40 C.F.R. § 720.25, EPA's response time takes at least 30 days. If the NOC did not claim the chemical identity as confidential, EPA typically does not publish notice of the NOC for 30 to 60 days following receipt of the NOC, delaying a future manufacturer from even learning that the PMN substance has been added to the Inventory.[23]

E. EPA Has Discretion and Authority to Issue a Non-Order SNUR to Address Activities Not Described in the PMN

1. EPA Does Not Have to Consider Possible Activities of Future Manufacturers and Processors in Evaluating a PMN

The term "conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen" to be manufactured, processed, distributed, or disposed of. The phrases "as determined by the Administrator" and "reasonably foreseen" give EPA discretion to select the conditions of use it will consider in making a risk determination, whether under section 6 or under section 5. Thus, EPA may, and should, leave the evaluation of the activities of future manufacturers and processors to its consideration of whether or not to promulgate a SNUR for the PMN substance following the end of the review period.

EPA has authority to select the conditions of use which it will consider in making risk determinations. EPA made that clear in the preamble to its risk evaluation regulations under section 6. There it acknowledged that some commenters had argued that every condition of use must be evaluated, while others countered that EPA may select particular conditions of use for the scope of its risk evaluations. After thorough consideration of the issue, EPA concluded that it had discretion to focus its risk evaluations on particular conditions of use. This conclusion was based in part on the definition of "conditions of use," which refers to "the circumstances, as determined by the Administrator." EPA found, reasonably, that "the determination will inevitably involve the exercise of some discretion."[24]

---

[23] See, e.g., 83 Fed. Reg. 116 (Jan. 2, 2018) reporting NOCs received in October, 2017.

[24] 82 Fed. Reg. 33726, 33729 (July 20, 2016). Notably, EPA stated in the final rule "that it [will] always [include] an evaluation of the conditions of use that raise greatest potential for risk." Id. at 33728.

That discretion remains as EPA makes risk determinations for a PMN substance under section 5. EPA has the discretion to make a "not likely to present" determination based on the activities described in the PMN, while leaving consideration of risks arising from possible activities of future manufacturers and processors after the substance is added to the Inventory for later consideration in the context of a SNUR.

As explained in section I.B.3.c of these comments, Congress expected EPA to make decisions about PMNs based on the activities described in the PMN and reasonably foreseeable extrapolations from those activities (and not speculation about possible activities of future manufacturers and processors):

> Consistent with existing law, the PMN submitter must provide EPA all available relevant information, including information on the intended conditions of use and reasonably anticipated exposures. The Committee intends that the review of the PMN should be conducted in that context.[25]

The implication of this statement is that possible activities of future manufacturers and processors of a PMN substance do not preclude a "not likely to present" finding for the PMN.

2. Section 5(e) Orders Based on Possible Uses by Future Manufacturers and Processors Would Have Essentially No Regulatory Effect

The action urged by some stakeholders -- having EPA issue a section 5(e) order where it has concerns about possible activities of future manufacturers and processors -- has a significant practical problem: it would be completely ineffective.

Consider an example where EPA finds that a PMN substance may present an aquatic hazard but the PMN submitter would not release the substance to water. Other manufacturers or processors of the substance might have different processes that would release the substance to water, creating potentially problematic exposure to aquatic organisms.

A section 5(e) order prohibiting the PMN submitter from releasing the substance to water would have no practical effect, since the PMN submitter was not going to do that anyway. Section 5(e)(1)(A) directs EPA to prohibit or restrict activities that "may present" an unreasonable risk "to the extent necessary to protect against an unreasonable risk." It is not "necessary" to order a PMN submitter to utilize the exposure controls it has certified that it plans to use. This is particularly the case where EPA plans to make a SNUR for the PMN substance effective shortly, given that the SNUR will mandate use of those exposure controls (without prior submission of a SNUN and EPA's review of it).

In addition, a section 5(e) order would have no effect on subsequent manufacturers or processors of the substance, who are the persons whom EPA wants to restrict. Since they would not be signatories to the order, they would remain unaffected by it. EPA would still have to promulgate a SNUR in order to restrict their potential releases of the substance to water.

---

[25] Senate Report at 15.

Note, however, that a "may present" finding in such a situation would delay completion of the PMN review process by months while EPA develops, negotiates, and then issues the section 5(e) order. The PMN submitter, who would not release the substance to water, would be held up for months from reaching the market due to the purported need to prohibit the submitter from releasing the substance to water.

3. A SNUR Is the Appropriate Means by Which to Evaluate Possible Activities of Future Manufacturers and Processors

Of course, EPA may consider the "conditions of use" of future manufacturers and processors of a PMN substance after the substance has been added to the Inventory. Congress intended EPA to use SNURs for this purpose, however, not section 5(e) orders. This is clear from section 5 itself.

Under section 5(a)(2)(D), before promulgating a SNUR, EPA must consider:

> the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

This phrase is strikingly similar to the definition of "conditions of use." The phrase "reasonably anticipated" is synonymous with the phrase "reasonably foreseen."[26] The phrase "manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance"' is synonymous with the following from the definition of "conditions of use": "the circumstances ... under which a chemical substance is ... to be manufactured, processed, distributed in commerce, used, or disposed of."

In other words, EPA must evaluate the "reasonably anticipated"/"reasonably foreseen" conditions of use of a PMN substance by manufacturers and processors after the substance has been added to the Inventory, but in the context of evaluating the need for a SNUR. There is nothing to be gained by having EPA make the exact same evaluation in evaluating a PMN, particularly since a section 5(e) order in that situation would have no practical effect, as discussed above. Congress did not mandate such an unnecessary duplication of effort.

Instead, it called for EPA to use rulemaking, through promulgation of a SNUR, to make decisions about any risks posed by the activities of persons (in addition to a PMN submitter) who may manufacture or import a PMN substance. This is appropriate, since in reviewing a PMN EPA can only speculate about possible actions by future manufacturers and processors. A rulemaking, even a direct final rulemaking, affords all stakeholders the opportunity to provide EPA with information prior to the time that it imposes restraints on persons other than the PMN submitter.

---

[26] The phrase "reasonably be anticipated" appears in section 5(a)(3)(B)(ii)(II) and section 5(e)(1)(A)(ii)(II), both related to a "substantial quantities" determination, as well as in section 4.

4. EPA May Make a "Not Likely to Present" Determination Even if It Has Concerns About Possible Activities of Future Manufacturers and Processors, Without Waiting for a SNUR to Take Effect

Even if it has concerns about possible activities by future manufacturers and processors of a PMN substance, EPA may make a "not likely to present" finding based on the activities described in the PMN without waiting for a SNUR for the substance to take effect. As noted above, for decades EPA did exactly that prior to enactment of the LCSA.

In 793 instances, it decided not to issue a section 5(e) order (in effect, it made a "not likely to present" finding) for a PMN substance and then proceeded to promulgate a SNUR for the substance based on concerns about possible future activities of others after the substance was added to the Inventory. In none of those 793 instances did EPA feel compelled to extend the PMN review period or delay making its "not likely to present" finding, until the SNUR was in effect.

The LCSA does not mandate a different practice. The requirement to make a "not likely to present" finding when deciding not to issue a section 5(e) order or to take action under section 5(f) addresses transparency about EPA's decision making in that situation, but make no change in substantive criteria. Thus, the only new language that bears any relevance is the "reasonably foreseen" language in the definition of "conditions of use."

Clearly, EPA has discretion to address t concerns about future manufacture or processing through a SNUR, rather than through review of a PMN. Congress regarded a SNUR as the more appropriate context for addressing those concerns, rather than the PMN context. In any case, EPA clearly has discretion to determine that the potential for the PMN submitter not to utilize those controls, during the few months after the PMN substance is added to the Inventory and before a SNUR for the substance becomes effective, is "not likely" to present an "unreasonable" risk. The risk is neither likely nor unreasonable.

F. EPA Should Improve the Process for Promulgating Non-Order SNURs

In ACC's view, the major problem with EPA's current conception of a non-order SNUR is that it will not terminate the PMN review period until the SNUR becomes effective. EPA would thus complete its review of a PMN but delay issuing its "not likely to present" finding until the SNUR becomes effective months later. This delay is contrary to section 5.

EPA should improve the non-order SNUR process by issuing its "not likely to present" finding as soon as it completes its evaluation of the PMN, then initiate rulemaking for a SNUR as soon as practicable within the next 90 days..

1. EPA Should Not Delay Issuing Its "Not Likely to Present" Finding Until a SNUR Becomes Effective

a. Delay Would Contravene Section 5

EPA's planned delay in issuing a "not likely to present" finding until a SNUR becomes effective would contravene multiple requirements in section 5,which direct EPA to issue its determinations within 90 days or as soon as possible thereafter.

In considering changes to section 5, Congress emphasized the importance of EPA completing its review of a PMN within 90 days "to the maximum extent practicable":

> The Committee intends the amendments to section 5 to ensure that EPA conducts an appropriate review of the potential health and environmental effects of new chemicals, while supporting the ability of manufacturers and processors to innovate and bring to market new chemicals and products through a flexible, targeted review process. The Committee notes that ... consistent with current law the Agency should continue the practice of completing new chemical reviews within 90 days to the maximum extent practicable.[27]

To emphasize the importance of the 90-day deadline, Congress amended section 5 in several ways. In section 5(i)(3) it added a definition of the new term "applicable review period":

> For purposes of this section, the term "applicable review period" means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

Since EPA has rarely taken action under either subsection (b)(1) or (c), this definition generally limits the "applicable review period" to 90 days.

Section 5(a)(1)(B) provides that a PMN submitter "may" manufacture a new chemical substance if it submits a PMN at least 90 days ahead of time and EPA makes a "not likely to present" finding "within the applicable review period," i.e., generally 90 days:

> A person may take the actions described in subparagraph
> (A) if—
> (i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and
> (ii) the Administrator—
> (I) conducts a review of the notice; and

[27] Senate Report at 14-15.

(II) makes a determination under subparagraph (A), (B), **or (C) of paragraph (3)** and takes the actions required in association with that determination under such subparagraph **within the applicable review period**.

(Emphasis added.) Section 5(a)(3)(C) requires that if EPA makes a "not likely to present" determination, it must do so "within the applicable review period," i.e., generally 90 days, after which time "the submitter of the notice may commence manufacture":

> **Within the applicable review period**, subject to section 18, **the Administrator shall review such notice and determine**— ...
> (C) **that the relevant chemical substance or significant new use is not likely to present an unreasonable risk** of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, **in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.**

(Emphasis added.) Section 5(a)(4)(A) adds a consequence if EPA fails to meet its obligation to make any "not likely to present" finding within 90 days – a refund of the PMN fee:

> If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b), and the Administrator shall not be relieved of any requirement to make such determination.

EPA routinely avoids the obligation to issue "not likely to present" findings within 90 days by requesting the PMN submitter to "suspend" the running of the review period while EPA continues its review of the PMN. This suspension technique is arguably contrary to the foregoing provisions of section 5. It can be justified only on the basis of practical necessity, since commonly EPA has not been able to make its determinations within 90 days (or even 180 days). Given the fact that withdrawal of a PMN is the only practical alternative to a suspension, it is not surprising that the vast majority PMN submitters agree to suspension requests.

The justification for a suspension does not apply in the case of a non-order SNUR, however. In that case, EPA has already completed its review of the PMN and determined that the PMN substance is "not likely to present" an unreasonable risk. It is simply waiting to issue that finding until the SNUR can become effective. This delay in completion of the applicable review period after all review of the PMN has been completed is inconsistent with section 5(g), which provides that once EPA makes its "not likely to present" finding,

> notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use.

Furthermore, section 5(g) also provides:

> Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

Clearly, issuance or publication of a "not likely to present" finding is a formality that may not hold up the PMN submitter's ability to commence non-exempt manufacture. Yet EPA's plan to delay making the finding until the SNUR becomes effective would rely on that formality to delay by months the submitter's ability to commence non-exempt manufacture.

b. Delay Would Be Self-Defeating

EPA plans its non-order SNUR to be an alternative to issuing an unnecessary section 5(e) order (and not, as some stakeholders have assume, as a replacement for section 5(e) orders). As noted, unnecessary section 5(e) orders needlessly consume resources of EPA and the PMN submitter and result in delay without meaningful result. Yet PMN submitters who are offered a choice may rather sign an unnecessary section 5(e) order and commence manufacture sooner rather than not sign such an order and not commence manufacture until a SNUR becomes effective months later. For example, some PMN substances represent significant innovations with internal commercial launch expectations, and some submitters may prefer to go the consent order route simply to assure some certainty in the review process. Other submitters may prefer the non-order SNUR process for other reasons, particularly when EPA makes a "not likely" determination.

Currently, section 721.170 sets out a lengthy timeline for promulgation of a non-section 5(e) SNUR. It targets publication of a direct final rule for 270 days (9 months) after receipt of an NOC. Following publication of a direct final rule in the Federal Register, stakeholders will have 30 days in which to comment. If no adverse comments or notices of intent to comment adversely are received within that period, the direct final rule will become effective 30 days after the comment deadline (11 months after receipt of the NOC). If instead an adverse comment or notice of intent to comment adversely is received, EPA will withdraw the direct final rule, but probably not until nearly 60 days after publication of the rule.[28] It will then publish a proposed rule, with no deadline for doing so, with another 30-day comment period. EPA may then take months to consider any comments received and promulgate a final rule, which then will become effective 30 days after publication. In some instances EPA has taken 11 months and longer from the publication of a direct final rule to complete rulemaking.[29]

---

[28] For example, in the most recent withdrawal of a direct final SNUR, EPA waited virtually the entire 60-day period prior to publishing a notice withdrawing the final rule. 82 Fed. Reg. 6277 (Jan. 19, 2017), withdrawing direct final SNURs published at 81 Fed. Reg. 81250 (Nov. 17, 2016).

[29] For example, one of the two direct final SNURs withdrawn on January 19, 2017, 40 C.F.R. § 721.10927, became the subject of a proposed rule published nearly six months after withdrawal of the direct final SNUR, 82 Fed. Reg. 26644 (June 8, 2017). EPA published a final rule in October, nearly 10 months after withdrawal, 82 Fed. Reg. 45990 (Oct. 3, 2017), but the final rule did not become effective until November 2, 2017, nearly a year after publication of the direct final rule. EPA still has not

In these cases, a section 5(e) order would have no practical regulatory effect on the submitter since usually the submitter would be willing to commit to the exposure controls that an order would require. The time spent waiting for EPA to propose, review, negotiate, and issue a section 5(e) order would be months less than the year or more sometimes required for a SNUR to become effective. ACC is already aware of PMN submitters who have asked for a section 5(e) order where EPA offered a non-order SNUR with the requirement to hold off on manufacture until the SNUR became effective.

2. EPA Should Make Its "Not Likely to Present" Finding Upon Completion of Its PMN Review and Expedite Promulgation of a SNUR

Instead of waiting for a SNUR to become effective, EPA should comply with section 5 and issue its "not likely to present" finding within 90 days of submission of the PMN to the extent practicable, and earlier than 90 days if possible. Under section 5(g), this will permit the PMN submitter to commence manufacture immediately, even if a portion of the 90-day review period remains.

EPA should also expedite promulgation of a SNUR. In a non-order SNUR context, EPA is not subject to section 5(f)(4), which requires EPA to initiate a SNUR rulemaking (if it plans to adopt a SNUR) within 90 days of issuing a section 5(e) order. But EPA should similarly plan to initiate rulemaking for a SNUR in a non-order SNUR context within 90 days of making its "not likely to present" finding. Initiation of rulemaking should be in the form of a direct final rule.

To be able to initiate rulemaking within that time period, EPA should begin its consideration of a non-order SNUR during the PMN review period, rather than waiting until after it ends (upon issuance of the "not likely to present" finding).

3. EPA Should Take Other Steps to Expedite Promulgation of a SNUR

Under section 721.170, EPA does not publish a proposed rule at the time it publishes a direct final SNUR. EPA could expedite the process if it were to publish a proposed rule at the same time as it publishes the direct final rule, as it has done in other instances.[30]

EPA should shorten the time targeted for publication of a direct final non-order SNUR. Section 721.160(d) calls for issuance of a direct final rule within 180 days after receipt of an NOC

---

published a proposed SNUR for the other direct final SNUR withdrawn on January 19, 2017, 40 C.F.R. § 721.10942.

[30] For example, EPA published a proposed rule on the same date as the direct final rule for rules under Title VI of TSCA. See update to voluntary consensus standards, 82 Fed. Reg 49287(Oct. 25, 2017) (direct final rule) and 82 Fed. Reg. 49302 (Oct. 25, 2017) (proposed rule); labeling relief, 82 Fed. Reg. 31922 (July 11, 2017) (direct final rule) and 82 Fed. Reg. 31932 (July 11, 2017) (proposed rule); extension of compliance dates, 82 Fed. Reg. 23735 (May 24, 2017) (direct final rule) and 82 Fed. Reg. 23769 (May 24, 2017) (proposed rule).

following issuance of a section 5(e) order, whereas 40 C.F.R. § 721.170(e) calls for issuance of a direct final rule within 270 days after receipt of an NOC following a decision not to issue a section 5(e) order. EPA should target an even shorter timeframe.

EPA should not shorten comment periods to less than 30 days, however, nor make final rules effective in less than 30 days after publication, as required by the Administrative Procedure Act.[31]

Such changes would result in a win-win-win situation:

- PMN submitters would benefit from being able to offer their PMN substances for commercial distribution relatively quickly. They would also benefit by having all manufacturers and processors of the PMN substance be subject to the same requirements for exposure controls.
- EPA would benefit by conserving its resources and by ensuring that public health and the environment are protected while avoiding creation of unnecessary economic barriers to technological innovation.
- The public would benefit by access to technological innovation under protective conditions.

V. Comments on EPA's Draft PMN Review Documents

A. The Draft Points to Consider Document

ACC is appreciative of EPA's work preparing its Points to Consider document. This document should provide a useful tool for submitters and greatly facilitate the quality and value of pre-submission consultation. We recommend that EPA make the following additional modifications.

- **Submission of studies:** The Points to Consider document should provide additional guidance to submitters that they be prepared to explain what studies are available and to summarize their findings as part of the pre-consultation process. If robust summaries are available, it may be more helpful to bring the robust summary in lieu of the full study report. Points to Consider should also discuss when EPA will likely request the full study as part of the PMN submission process, which offers the submitter more time to obtain and prepare the submission if needed. This discussion should address practices for managing data ownership of raw data and study reports as well as confidential data. Points to Consider should also clarify that EPA will accept and consider robust study summaries that comply with OECD guidelines.

- **Analog choice:** Points to Consider should offer a template narrative description about analog choice as guidance for submitters. The document should also explain that such narrative descriptions facilitate EPA's speed and completeness of review. The document

[31] See 5 U.S.C.§ 552(d).

should explain that EPA will not undertake its analog search until the PMN is initiated, so any pre-work evaluating analog choices and supplying a rationale conducted by the submitter may help accelerate EPA's subsequent review.

- **Typical testing or case studies:** EPA has indicated that it cannot definitively indicate what testing or data may be required in its review of the PMN. It would be helpful, however, if Points to Consider could offer several additional examples or scenarios where testing typically might be required, and the basis for this rationale. This could be included as part of the Generic Scenarios document (which EPA should regularly update). Submitters benefit from a clearer understanding of when EPA is likely to require testing, and what the boundaries and protocols for such testing will be.

- **Rationale for measured vs. modeled data:** EPA has generally expressed a preference for measured data, or a suggested model, or use of an analog with respect to human health and ecotoxicity. This should be articulated in Points to Consider, along with a supporting rationale – and an accompanying, clear explanation of when and why modeled data may be preferred over measured data.

- **Explanation of the significance of structural alerts in the review process:** EPA has indicated that in the event of a structural alert, it is particularly interested in obtaining full study data. It would be useful for Points to Consider to fully explain: (1) what a structural alert is; (2) how the alert is triggered; (3) what concerns this may raise for EPA; (4) what additional study information EPA will be interested in obtaining, and why.

- **Substantiation for suggested engineering and exposure controls:** EPA has indicated that in addition to recommended engineering and exposure controls, it is helpful if submitters offer a rationale and some level of substantiation for the approaches offered. Points to Consider should offer guidance on how submitters can provide both a rationale and substantiation.

B. New Chemicals Decision-Making Framework

EPA released its working approach to making determinations under Section 5 of TSCA in November 2017 entitled New Chemicals Decision-Making Framework. We offer specific comments on the outline, and in particular, the proposed content for the Manual below.

Introduction – The Lautenberg Amendments to TSCA have a number of important elements that require decisions by EPA and inform how those decisions are made. It would be helpful if the introduction would set these out up front (or, if EPA intends to integrate the Decision-Making Framework into the New Chemicals Decision Guidelines Manual, that it do so in that document):

- Affirmative determination: TSCA now requires an "affirmative" determination by EPA on new chemicals decisions. In short, "dropped" PMNs and the ability to begin manufacturing a chemical if EPA reaches no decision within the review period is no

longer allowed; EPA must reach a determination first.

- Sufficient information: There must be sufficient information for EPA to make a reasoned evaluation of health and environmental effects. Sufficient information can include representations or commitments of the submitter. EPA must ultimately decide, in each submission, whether the body of information is, or is not, sufficient to inform a reasoned evaluation.
- Reasonably available information: EPA is required to consider reasonably available hazard and exposure information to carry out Section 5. The application of this term requires EPA to make a decision whether reasonably available information has been identified and considered.
- Reasonably foreseen: This term is equivalent to "reasonably anticipated." The application of this term requires EPA to make a decision regarding what is or is not reasonably foreseen.

Decisions must be risk-based, and they are also intended to be made within 90 days (for PMNs) of submittal.

Overall Framework – It would be helpful for EPA to list all the decision options/outcomes in sequence here, in advance of more detailed discussion. Rather than offering the decision tree using sufficiency of information as the starting point, EPA might list the four available determinations and work backwards from these.

Discussion of what is known/intended/reasonably foreseen for the submitter versus non-submitters – Fundamentally, the New Chemicals program is centered on the request of a single manufacturer asking EPA for permission to begin manufacturing a chemical. Congress intended this review and decision to be made within 90 days. EPA's tool to regulate other entities who wish to begin manufacture or import of the same substance is a SNUR.

EPA's decision framework properly acknowledges that with respect to a submitter's proposed activity (manufacturing, processing, distribution in commerce, use and disposal of a substance), EPA has the information it needs from the PMN itself. Submission of the PMN creates enforceable obligations; notably, EPA requires submission of all test data in the submitter's possession or control, and omission of a study is subject to enforcement action. As noted above in Section IV.C., a submitter who misrepresents its intentions on a PMN is potentially subject to enforcement: withholding information or submitting false or misleading information with regard to a PMN or Significant New Use Notice (SNUN) is a level 1 TSCA violation (per day) in EPA's TSCA Section 5 Enforcement Response Policy.[32] For exemption applications, statements supporting the exemption become binding on the submitter when EPA approves the exemption application.[33]

Accordingly, the intended uses of a submitter can be reasonably determined by its own Section 5

[32] TSCA Section 5 Enforcement Response Policy, https://www.epa.gov/sites/production/files/2016-06/documents/amendedtscasection5-erp.pdf.

[33] See Instruction Manual for Reporting Under the TSCA Section 5 New Chemicals Program at I.F., Binding Boxes.

submission. The submitter has a strong compliance incentive for its PMN to be accurate, since the "addition" of another use outside the scope of the PMN and certainly within the near term after the NOC is submitted invites enforcement exposure. As EPA properly notes, any concerns about the manufacturer of the chemical by third parties can be addressed in a non-order SNUR.

Level of uncertainty to support determination: For the Section 5 program to work as anticipated by Congress, submissions would be supported by sufficient information to inform a reasoned determination of the compound, particularly since EPA applies modeling and other techniques to inform its review. There is nothing in the legislative history to suggest that EPA was pushing chemicals through the program (or "dropping" PMNs) in sizable numbers due to lack of sufficient information.

For that matter, there is nothing in the legislative history to suggest that there was any change in the level of certainty needed to support a determination that a chemical is sufficiently low risk that manufacturing may begin. The volume of "not likely to present" determinations under the amended statute should thus roughly correlate to the number of dropped PMNs before amendment.

EPA's discussion at footnote 3 in the Decision Framework, however, confuses matters. The agency suggests that the level of uncertainty in a "not likely" determination could be greater than in a "presents" determination. But the level of certainty in a "not likely" determination could also be higher (the statute does not allow the award of any other designation, such as "does not present" or "will not present" under Section 5). What EPA leaves out of this discussion is that there may be no space at all between a "presents" determination and a "not likely to present determination" – in a given situation, these may operate in a near binary manner. For that matter, since this determination must occur in the context of conditions of use, a submitter's agreement to manufacture in accordance with changes to the PMN may itself be sufficient to modify a "presents" determination to a "not likely to present" determination, taking that additional information into account. We suggest EPA delete the last two sentences in footnote 3 for greater clarity. If footnote 3 is a reflection of current EPA policy, we strongly recommend that EPA publish, for public comment, a complete rationale for this approach.

C. Draft New Chemicals Decision Guidelines Manual

EPA has released an outline of its Draft New Chemicals Decision Guidelines Manual as part of this docket and requested comment.[34] We note, as a preface, that the issuance of decision guidance that explains and makes transparent the decision-making process of an agency is both valuable and well-established.[35] It is also considered a highly beneficial transparency measure

[34] https://www.epa.gov/sites/production/files/2017-11/documents/outline_of_new_chemicals_decisions_manual_v3.pdf.

[35] See, e.g., FERC, Risk-Informed Decision Making Guidelines (March 2016), https://www.ferc.gov/industries/hydropower/safety/guidelines/ridm/risk-guide/chapter-1.pdf (used to identify, analyze, assess, and manage the risks associated with FERC-regulated dams); FDA, Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators and Food and Drug Administration Staff (January 2017), (explains the principal factors FDA considers when assessing the

for agencies to make their policies available to the public, as well as to agency staff.[36] We applaud EPA for its efforts to make its New Chemicals review process more transparent to the public and to submitters.

We offer specific comments on the outline, and in particular, the proposed content for the Manual below.

Introduction (Part 1) – We suggest that the introduction be significantly shortened, and that separate sections address the process and timelines for review. The statutory determination framework set out in Part 14 (Risk Management) should not be repeated in the same detail in the introduction (currently at 1.6).

Purpose (Part 1.0) – Presumably, the New Chemicals Decision Guidelines Manual is one of many guidance documents that will support administration of the New Chemicals program. We are encouraged that EPA acknowledges that it is in the process of updating its procedures, policies, and decision guidelines to reflect the Lautenberg amendments to TSCA. ACC encourages EPA to use this process to create an updated compendium of applicable policies, procedures, and guidance in the New Chemicals program; to ensure that guidance is consistent across documents; to ensure appropriate cross-references of relevant discussions; and to ensure that policies are easily searchable and findable by regulated entities. To that end, it would be helpful if both the Part 1.0 Purpose statement, as well as Appendix C (Sources of Information) are suitably comprehensive.

Applicability (Part 1.1) – It would be helpful if the Manual would include a short introduction describing what a new chemical is under TSCA as well as what regulated entities are affected by the New Chemicals Program. Cross-references to EPA's website would be appropriate.

TSCA Section 5 Authority (Part 1.2) – We suggest that EPA consolidate the discussion at Part 3, entitled TSCA Section 5 Applicability, with this section. From the standpoint of the regulated community, it makes good sense to discuss chemicals that are subject to Section 5 and those not subject to Section 5 in the same part of the Manual.

Pre-Notice Consultation (Part 2) – We support EPA's proposal to describe the new chemicals review process using a chronological timeline. We suggest, however, that the body of the document truncate the Guidelines Manual into 4 major segments:

- Pre-submission (including discussion of the voluntary pre-notice consultation process)
- Submission and EPA review (cross-referencing advice on PMN preparation and submission; outlining the submitter's obligation to submit test data; and reviewing EPA's

---

benefits and risks of IDE applications for human clinical studies), https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM451440.pdf.

[36] ACUS Recommendation 92-2, Agency Policy Statements (1992) (policy statements are "[i]mportant tools for guiding administration and enforcement of agency statutes and for advising the public of agency policy.").

risk assessment process and steps)
- EPA Determination (outlining the statutory requirements and agency process to reach determinations)
- Risk Management

Conditions of Use (Part 4) – We suggest several modifications to the outline. First, it would be helpful for EPA to explain the statutory definition and requirements, including EPA's discretion to make determinations regarding conditions of use. Second, it would be helpful for EPA to explain that by statute, it must do more than characterize conditions of use; it must make a determination of them for purposes of the new chemicals review. Third, it should explain that "known" uses do not exist in the new chemicals context since manufacture has not yet been initiated. EPA should also include an appropriate discussion of "reasonably foreseen" from the working New Chemicals Decision-Making Framework in this section.

Biotechnology Submissions – EPA may wish to consider whether the document would be clearer and more compactly presented if biotechnology submissions were to have a stand-alone discussion section.

Non-animal Methods, Fees – EPA has yet to publish its proposed fees rule, which presumably may have an effect on fees under Section 5, and likewise is still developing its non-animal strategy. Nonetheless, it would be helpful for the Manual to reference these potential developments, and it would be helpful to update the Manual at the appropriate point to include additional discussion.

VI. Additional Specific Comments

A. Chemical Categories

EPA should update the 2010 Chemical Categories document.[37] Doing so would enable EPA to communicate more effectively its concerns and recommended testing for the categories listed in the 2010 document and to add additional categories. This in turn would enable potential PMN submitters to identify potentially problematic candidates for a PMN. They could then either halt further R&D on them or else conduct testing to confirm or refute EPA's concerns based on their respective chemical categories.

B. Low Molecular Weight Species

EPA should clarify and justify its concerns about low molecular weight species in or accompanying PMN substances.

The Chemical Categories document asserts, "Typically, concerns are confined to chemicals with molecular weights <1,000 whenever inhalation exposure to humans or environmental release is

[37] EPA, TSCA New Chemicals Program (NCP) Chemical Categories (last revised August 2010), https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf.

expected, and to species <500 when dermal exposure to humans is expected." PMN submitters have found EPA to be concerned about species with higher molecular weights than indicated by this statement. EPA should clarify the scope of molecular weights likely to be of concern and explain the basis for that scope.

EPA should clarify the Inventory status of unintended low molecular weight species and unreacted monomers produced in the course of manufacturing a PMN substance. PMN submitters typically regard them as impurities exempt from PMN review or coproducts that are already on the Inventory, but in some cases EPA appears to be basing its concerns on these substances.

C. Worker Health and Safety Requirements

EPA's SNUR regulations in 40 C.F.R. §§ 721.63 and 721.72 address important aspects of protection for workers. EPA should complete its rulemaking to update those provisions.[38] However, in doing so, it should take into account the comments by ACC and others.

This rulemaking has carryover significance for the PMN program, as many of the Protection in the Workplace provisions of the boilerplate section 5(e) order used by the EPA staff similarly need to be updated. For example, the hazard communication section does not appear to have been revised in light of OSHA's 2012 amendments to its hazard communication standard.[39]

D. Releases to Water

EPA should clarify its concerns about predictable or purposeful releases to water. About half of all SNURs, and thus probably about half of all section 5(e) orders, include a "release to water" provision.

In section 5(e) orders, default "no release to water" provisions are not appropriate. Absolute "no release" requirements are conceptually very difficult for PMN submitters to deal with, given the lack of monitoring capability. A "no release" provision may lead to extended discussion with EPA, delaying issuance of the 5(e) order and the submitter's ability to enter the market. Even where a PMN submitter has no releases to water, a "no release" provision can cause problems for its customers, and a subsequent SNUR for the PMN substance is likely to include the same prohibition on "release to water" as found in the section 5(e) order.

As a threshold matter, water release provisions are not appropriate at all if the submitter's activity cannot result in a release to water as a function of the manufacturing process. In cases where a release is possible, a release provision should be appropriately tied to the specific information in the PMN and the intended manufacturing and management descriptions offered by the submitter. In addition, the release provision should take risk into account consistent with the provisions of section 26 of TSCA. As part of the pre-submission process, if release to water

[38] The proposed rule was published at 81 Fed. Reg. 49598 (July 28, 2016).
[39] The boilerplate section 5(e) order is available at https://www.epa.gov/sites/production/files/2016-09/documents/co_all_purpose_preamble_and_consent_order_combined_9-1-2016_clean.pdf.

is identified as a possible concern, the submitter should be invited to propose a water detection method and proposed concentration, taking into account the technological feasibility of detection specific to the substance.

In addition, EPA should clarify that a "release to water" concentration relates to concentration in waters of the United States that receive the PMN substance. This is explained in technical terms in 40 C.F.R. §§ 721.90 and 721.91, but PMN submitters may have difficulty in understanding this concept, since they may want to monitor for concentrations upstream of receiving waters.

EPA should also provide resources to help PMN submitters calculate the expected concentrations of their PMN substances in waters of the United States. Examples and references to resources for estimating the flow rates of receiving waters such as rivers would be helpful. Section 721.91(b)(2) suggests use of NPDES permit information or U.S. Geological Survey data; EPA should make it easier for PMN submitters to find this information.

Given the current debate about the term "waters of the United States," EPA should provide examples of what it considers to be waters of the United States in this context. For example, would use of water containing the PMN substance for irrigation of agricultural fields be considered a predictable or purposeful release to waters of the United States if some of the water could foreseeably run off into nearby streams? If the PMN substance could reach groundwater and groundwater could be pumped up or migrate into waters of the United States, would that be a predictable or purposeful release to waters of the United States?

EPA should clarify whether use of a PMN substance in the Gulf of Mexico outside the three-mile limit would be subject to a "release to water" provision, given that TSCA jurisdiction extends only to the United States.

EPA should clarify the application of a "release to water" provision to a PMN substance that disassociates in wastewater into ions or that chemically reacts prior to release to waters of the United States.

EPA should confirm that spills are not "predictable or purposeful" releases to waters of the United States, even if spills are foreseeable. EPA has indicated:

> Purposeful or predictable releases to water would not include accidents or spills. This significant new use designation was not intended to prevent every single molecule of a subject chemical substance from being released to surface waters.

In contrast, EPA has explained:

> Any water releases of the PMN substance identified in the PMN would qualify as purposeful or predictable releases.[40]

[40] EPA, "Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules," 75 Fed. Reg. 56880, 56884 (Sept. 17, 2010).

This guidance should be made more widely available. EPA should incorporate it into a formal guidance document.

CONCLUSION

EPA has embarked on an aggressive implementation of the new provisions of section 5. While generally doing an excellent job with limited resources, EPA has misconstrued what section 5 now requires in a number of instances. It should ensure compliance with section 5 as written; exercise its discretion in a manner that both protects health and the environment and promotes the policies of section 2(c); and otherwise look to streamline what has become an over-lengthy and complicated process for reviewing PMNs and promulgating SNURs.

Comments of the American Chemistry Council on the New Chemicals Review Program Under TSCA as Amended

Docket No. EPA-HQ-OPPT-2016-0658

January 17, 2017

Michael P. Walls
Karyn M. Schmidt
Christina Franz
American Chemistry Council
700 Second Street, N.E.
Washington, DC 20002
(202) 249-6130

Of Counsel:
Mark N. Duvall
Beveridge & Diamond, P.C.
1350 I Street, N.W.
Washington, DC 20005
(202) 789-6090
mduvall@bdlaw.com

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The American Chemistry Council (ACC)[1] welcomes the opportunity to provide comments on the New Chemicals Review Program under the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[2] ACC submits these comments in response to EPA's notice announcing the December 14, 2016, public meeting on this subject and an opportunity to comment, 81 Fed. Reg. 86713 (Dec. 1, 2016).

These comments make the following points:

- The LCSA enhanced EPA's ability to scrutinize PMN submissions by codifying attention to potentially exposed populations, ensuring that EPA had sufficient information to make decisions, and to provide more transparency in decisions on PMNs. Congress left the standards for New Chemical review and decision-making fundamentally intact, retaining the unreasonable risk standard.

- Notwithstanding Congressional intention to leave the mechanics of this well-run program fundamentally intact, EPA has significantly changed its previous implementation of the New Chemicals Review Program since enactment of the LCSA in a manner inconsistent with congressional intent.

- The changes have created a substantial and growing backlog in the review of premanufacture notices (PMNs) for new chemicals, blocking the ability of businesses to manufacture and bring new chemistries to market in the United States.

- The changes have also introduced substantial structural problems to the operation of the new chemicals program. These include a sharply increased rate of section 5(e) consent orders; a corresponding sharp decline in the rate at which EPA allows PMN substances to be commercialized without a section 5(e) consent order; delays well beyond the 90 days allotted for PMN review -- even for chemicals that do not receive a section 5(e) consent order; and agency requests that submitters allow EPA more time than the 90 days allotted for review, which undercuts Congress' expectation that the review period will be prompt and the review efficient.

- The legislative history does not support EPA's heightened scrutiny of PMNs to explain

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an $812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

[2] Public Law 114-182 (June 22, 2016). References to TSCA in these comments are to TSCA as amended by the LCSA unless otherwise indicated.

decisions that a PMN substance is not likely to present an unreasonable risk. The LCSA made important changes to EPA's review of new chemicals, but did not change the legal standard applied in PMN reviews.

- EPA should expand its criteria for making a determination that a PMN substance is "not likely to present an unreasonable risk," since its current criteria are too limited. EPA apparently does not regard identification of exposure controls in the PMN to be sufficient for making that finding where it is possible, even though unlikely, that the PMN submitter would not actually impose those controls. This practice reduces the extent to which EPA reviews for risk rather than hazard and is not appropriate.

- The "not likely to present an unreasonable risk" standard is equivalent to the standard that EPA used for 35 years prior to enactment to decide that a section 5(e) consent order was not necessary. There is no statutory justification for EPA to use a more stringent standard post-enactment.

- EPA should reconsider its understanding of the term "conditions of use." It does not require EPA to consider uses of manufacturers or processors other than the PMN submitter and its direct customers. Both the language of section 5 and the LCSA legislative history direct EPA to consider only the uses of the PMN submitter and its direct customers. Consideration of other manufacturers and processors should be addressed through promulgation of significant new use rules (SNURs), as EPA has done for decades.

- EPA should pursue alternatives to section 5(e) consent orders. As an initial matter, immediately after the focus meeting, it should discuss with the PMN submitter what initial concerns EPA has; what additional information would be useful to resolve those concerns; and options for addressing those concerns, where the options include alternatives to a section 5(e) consent order.

- EPA should consider how the PMN "binding option" for controls can be used as an option to address controls that EPA considers critical to resolving its concerns and to avoid the need for a section 5(e) consent order. EPA should provide a simple mechanism for approving potential future changes to controls.

- EPA should resume promulgation of non-section 5(e) SNURs to avoid issuing unnecessary section 5(e) consent orders.

INTRODUCTION

ACC strongly supported enactment of the LCSA, including the limited amendments to section 5. Its members are committed to successful implementation of TSCA as amended. These comments are offered in that spirit.

The New Chemicals Review Program, set out in section 5 of TSCA, is the entry gate that allows new chemicals to be manufactured and used to make U.S. products. EPA has long had and exercised authority under TSCA to review chemicals for safety before they enter commerce. The basis for its decision-making, however, was not readily apparent to the general public.

ACC supports a robust review of new chemical substances under section 5. The LCSA changes to section 5 codify EPA's prior practice to assess potentially exposed populations, ensure that EPA has sufficient information to make section 5 decisions, and provide for more transparency in EPA's decision-making. The LCSA changes to section 5 do not fundamentally change how EPA was reviewing new chemicals for safety prior to entry into commerce; the safety standard of unreasonable risk with respect to health and safety considerations has not changed.[3]

Companies that research and develop new chemistries depend on a functioning, reliable New Chemicals Review Program to be able to bring these innovations to market. So do companies that want to use these new chemistries to build new products and deliver market solutions. Many new chemistries are developed specifically to deliver better performance or improved health or environmental attributes. A predictable and functioning New Chemicals Program is thus often explained as critical to U.S. innovation; it incentivizes development of new chemistries, which in turn make possible new product and technology applications, upgrades, and even breakthroughs.

Some stakeholders at the December 14 public meeting on section 5 seemed to suggest that industry support for a functioning and efficient program – necessarily one that protects and promotes U.S. innovation – means that industry puts profits ahead of health and environmental considerations. This is disappointing, has no basis in evidence, and is unfair. Like many stakeholders, ACC believes that the New Chemicals Review Program as it existed prior to enactment of the LCSA worked well. Importantly, Congress intended to preserve the fundamental operation of this program. It retained the review standards, codified EPA's practice of reviewing potential impacts of exposures on certain populations, and included new requirements for EPA to be more transparent about the basis for its decision making.

[3] At the December 14 meeting, EPA indicted that even before the LCSA was enacted, EPA had been conducting an internal assessment of the New Chemicals Review Program. EPA staff stated that this internal review has led to multiple changes in assumptions used in the PMN review process. This is the first time that EPA has suggested it is changing the way that it conducts scientific evaluations under saection 5. We note that the LSCA does, in fact, now require under section 26 that EPA use best available science and weight of the evidence in carrying out its reviews under section 5 of the statute. It is imperative that EPA explain the methods and assumptions used to conduct section 5 reviews under thesSection 26 scientific criteria. We urge EPA to do so as expeditiously as possible in light of Congress' expectation, under the LCSA, that the bases for EPA's determinations be transparent. Promptly updated guidance documents could help discharge this obligation.

Despite a rocky start since enactment of the LCSA, the section 5 program can work well again.

These comments are intended to assist EPA in adapting the program in a manner that is consistent with the statute and its legislative history; maintains EPA's high scientific standards; and successfully protects health and the environment while enabling innovative chemistry to reach the market after appropriate review.

DISCUSSION

1. EPA's Implementation of Amended Section 5 Is Creating Structural Problems, Not Just a Temporary Backlog

At the December 14 meeting, many participants complained about the large and increasing backlog of unresolved PMNs.[4] EPA responded that the backlog was merely temporary, due mainly to EPA's "resetting" the review clock for PMNs that were in the review process as of June 22, 2016, the date of enactment of the LCSA. ACC is concerned that the backlog and resulting delays are not temporary, but rather the result of structural problems in how EPA is interpreting amended section 5. The backlog is having serious adverse impacts on EPA, PMN submitters, and the public. It directly contravenes the Congressional intent that EPA should complete its review of PMNs in 90 days or less.

a. The Backlog Is Large and Growing

It is clear that there is a backlog, and it is growing, not shrinking, despite EPA having had over 6 months since June 22 to adjust to the statutory changes.

On June 22, EPA reset the review period for about 331 PMNs pending as of the day before enactment,[5] some of which had been pending since FY 2009.[6] Since then, the backlog has effectively doubled. During the period from June 22 through November 30, EPA received 327 PMNs that were not originally submitted prior to June 22, for a total of 658 PMNs.[7] (EPA has characterized the backlog as being about 500 PMNs.)[8] During the more than 6 months since June 22, EPA has completed its review of only 29 of those 658 PMNs.

At the December 14 meeting, Jeff Morris, Acting Director Office of Pollution Prevention and

---

[4] Additional comments about how the New Chemicals Review Program is no longer working well appear in Appendix 1. These are recent problems experienced by ACC members.

[5] See 81 Fed. Reg. 74784 (Oct. 27, 2016) (349 PMNs "received" during the period June 22 through June 30; 18 of these were new submissions, per the earlier report for June 2016, 81 Fed. Reg. 49976 (July 29, 2016)). At the December 14 meeting, Jeff Morris reported that 308 PMNs had their review periods reset on June 22.

[6] The PMNs whose review periods were "reset" include 2 from FY 2009, 3 from FY 2010, 3 from FY 2011, 15 from FY 2012, 11 from FY 2013, 26 from FY 2014, 62 from FY 2015, and the remainder from FY 2016.

[7] See 81 Fed. Reg. 49976 (July 29, 2016) (18 PMNs received between June 22 and June 30); 81 Fed. Reg. 57903 (Aug. 24, 2016) (48 PMNs received in July); 81 Fed. Reg. 79013 (Nov. 10, 2016) (41 PMNs received in August); 81 Fed. Reg. 79020 (Nov. 19, 2016) (43 PMNs received in September); 81 Fed. Reg. 85556 (Nov. 28, 2016) (36 PMNs received in October); 81 Fed. Reg. 91162 (Dec. 16, 2016) (141 PMNs received in November).

[8] At the December 14 meeting, Jeff Morris said that since June 22 "we have received about 200 more cases. So since enactment there have been 500 cases that we needed to evaluate under the new requirements of the law."

Toxics, reported:

> Of those 500, about 120, about one quarter of those are undergoing further review. And for the remainder, for hundreds of cases, we made preliminary determinations and action letters, over 100, now have gone out to companies identifying our preliminary determination ....[9]

In other words, in more than 6 months EPA has determined that close to half of the pending PMNs either will receive section 5(e) consent orders or are likely to do so, but it apparently has not completed its review of any of those PMNs.

During that same 6-month period, EPA has apparently made final determinations of "not likely to present an unreasonable risk" for only 29 PMNs. EPA now posts a log on its website identifying PMN substances determined to be "not likely to present an unreasonable risk." According to that log, from June 22, 2016 through January 10, 2017 (the date of the latest update), EPA has posted identification of only 29 such PMN substances (along with 26 microbial commercial activity notices (MCANs)).[10] Of those 29 PMNs, 12 were among those whose review periods were "reset," and 17 were submitted since enactment.

Thus, during a period of about 6 months, while the backlog doubled from 331 PMNs to 658 PMNs, EPA has completed its review of only 29 PMNs. Clearly, the backlog is large and it continues to grow.

b. The Backlog Reflects Structural Changes in EPA's Review of PMNs

One indicator that the backlog is not temporary is EPA's extraordinarily slow progress in identifying PMN substances that are not likely to present an unreasonable risk. Another is that EPA has substantially changed the previous ratio of the number of PMNs that receive a section 5(e) consent order to those that do not.

Prior to enactment of the LCSA, EPA typically "dropped" substances for which it did not plan to issue a section 5(e) consent order before Day 21 of the review period, during the focus meeting. "Dropping" a chemical was analogous to making a determination of "not likely to present an unreasonable risk," since the most commonly used basis for issuing a section 5(e) consent order before enactment was a determination that the PMN substance "may present an unreasonable risk." ACC and its members agreed, however, that there was an important lack of public information on the reason substances were "dropped" from additional review. The LCSA amendments address that transparency element.

---

[9] This and other quotations from EPA staff at the December 14 meeting are from an unofficial transcript of the meeting prepared by ACC from the close captioning provided by the software for those attending the meeting remotely (Transcript). ACC has corrected some obvious errors and added paragraph breaks. Additional errors likely remain. The transcript appears in Appendix 2. This quotation appears at page 3 of the Transcript.

[10] EPA Pre-Manufacture Notice Review Determinations under Amended TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-pre-manufacture-notice-review (last updated Jan. 10, 2017). The results show 7 determinations in July, 0 in August, 7 in September, 1 in October, 7 in November, and 7 in December.

Unfortunately, a total of 29 final PMN determinations that a substance is "not likely to present an unreasonable risk" in nearly 6 months is an astonishingly slow pace. Since EPA has no intention of issuing section 5(e) consent orders for these substances, the slow pace cannot be attributed to the time needed to develop, negotiate, and issue section 5(e) consent orders. Instead, EPA is simply taking much more time to review PMNs than before enactment, even for PMN substances of low concern.

Moreover, the time required to make an individual "not likely to present an unreasonable risk" determination is unacceptably long even as EPA gains experience under amended section 5. For the 29 PMNs whose review EPA has completed since June 22, the review periods ranged from 49 to 143 days, for an average of 90 days, i.e., the entire 90-day period allowed in the statute.[11] This is a worrisome situation, particularly since Congress was insistent that EPA complete its PMN reviews within 90 days or less, to the extent practicable, and presumably these are relatively simple reviews. The average of 55 days for decisions made in December is a welcome improvement, but is unclear of that pace can be sustained; the average in November was 91 days.

As for PMNs for which EPA is probably going to make a determination other than "not likely to present an unreasonable risk," since enactment, EPA has substantially increased the percentage of PMNs for which it expects to issue section 5(e) consent orders. Prior to enactment, EPA issued section 5(e) consent orders for about 4% of PMNs received and "dropped" (no further review) about 90% of the PMNs received; the rest were withdrawn by the submitter.[12] At the December 14 meeting, Jeff Morris indicated that about 120 PMNs are undergoing further review, with a section 5(e) consent order likely; that more than 100 action letters have been sent; and that EPA has made "hundreds" of "preliminary determinations" apparently indicating that a section 5(e) consent order is coming.[13] This suggests that EPA is considering issuance of section 5(e) consent orders for about half or more of all pending PMNs, an increase of over 1500% compared to past practice.

Significantly, EPA appears to have largely shifted its review of PMNs from an analysis of potential unreasonable risk to one of potential hazard. This change is not authorized by statute.

---

[11] For the 7 final PMN decisions made in July, all of which were for PMNs originally submitted prior to June 22, the average review period was 97 days (including the days prior to June 22). No final decisions were made in August. For the 7 final decisions made in September, of which 6 were for PMNs originally submitted prior to June 22, the average review period was 117 days (including the days prior to June 22). For the 1 final decision made in October, the review period was 89 days. For the 7 final decisions made in November, the average was 91 days. For the 7 final decisions made in December, the average was 55 days.

[12] According to EPA statistics, during fiscal years 1979 through 2015, EPA received 39,962 PMNs, of which 1,710 (4%) received section 5(e) consent orders and 2,068 (6%) were withdrawn by the submitter in the face of EPA action. That means that 36,194 (90%) of PMNs were neither withdrawn nor received a section 5(e) consent order. EPA, "Statistics for the New Chemicals Review Program under TSCA" (last updated Aug. 4, 2016), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

[13] Maria Doa, Director of OPPT's Chemical Control Division, confirmed at the meeting what is now obvious: "As Jeff mentioned, the number of [section 5(e) consent] orders will or have been increasing because they are issued for cases other than the not likely to present." Transcript at 8.

In many cases EPA has indicated that it will require a section 5(e) consent order to ensure that the PMN submitter actually uses the exposure controls addressed in the PMN, so that it places no weight on submitter assurances in the PMN. In many other cases, EPA has indicated that it will require a section 5(e) consent order based on concern about the possible lack of exposure controls implemented by potential manufacturers other than the PMN submitter and their customers, after the substance is added to the Inventory. Since the PMN submitter usually cannot provide information on the exposure controls that such persons would use, EPA gives no weight to the exposure controls that they might use. The result is that many or most PMNs are effectively being regulated through section 5(e) consent orders on the basis of hazard, without regard to the exposure controls described in the PMN. This is substantial change from past practice and is a major cause of the backlog.

In short, EPA is taking an increasingly long time to make a "not likely to present an unreasonable risk" determination and is doing so in fewer cases, down from 90% of cases to perhaps less than 50% of cases. It is increasing the number of PMNs likely to receive a section 5(e) consent order, up from 4% of cases to perhaps more than 50% of cases, if not more. These are radical shifts in how EPA makes decisions under the New Chemicals Review Program. They have nothing to do with the fact that EPA "reset" the review period for then-pending PMNs on June 22. They strongly suggest that over time the current backlog will continue to grow, and grow substantially.

ACC accepts that the LCSA amendments to section 5 provide the Agency more authority to carefully scrutinize new chemical submissions. But the amendments also make clear Congress' intent that PMN review occur within the statutorily-mandated 90-day period. The changes EPA has made in the program strongly suggest that the 90-day review period will be met in only a minority of cases.

c. The Backlog Has Serious Implications

A large and growing backlog has serious implications for EPA, PMN submitters, and the public.

Having many more PMNs to address than before enactment increases the burden on EPA staff. The burden is exacerbated by EPA's apparent view that the majority of these are likely to require development, initiation, and issuance of section 5(e) consent orders. EPA has many new responsibilities under the amended TSCA. It needs to allocate its limited resources to those new responsibilities rather than double the New Chemicals Program staff to address the doubled, and growing, PMN backlog. The backlog means that the New Chemicals Program, previously widely regarded as both effective and efficient, is largely paralyzed. That was not the intent of Congress in amending section 5.

The delays mean that PMN submitters cannot get their new chemicals onto the market for extended periods, and often then only under onerous conditions set in a section 5(e) consent order. In some cases, those conditions may preclude commercialization, as unproven new chemicals burdened by a section 5(e) consent order cannot compete with existing chemicals that have no such burden, even though the new chemicals may have an improved health or

environmental profile, or be more effective. This can have a significant impact on U.S. innovation in the chemicals area.

Finally, the delays also mean that the public and the environment cannot benefit in a timely manner from the economic, health, and/or environmental advantages that new chemicals held up in the PMN backlog would provide if they were allowed to enter the market.

The current situation does not meet the requirements of section 2(c) that EPA must "carry out this Act in a reasonable and prudent manner" and "shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this Act."

d. The Backlog Contravenes Congressional Intent that EPA Make PMN Determinations in 90 Days or Less

The current situation is not what Congress intended. The changes to section 5 – particularly the ability for the agency to identify those PMNs for which insufficient information exists to make a decision – indicate an enhanced ability to scrutinize new chemicals. But in amending section 5, Congress also emphasized the need for EPA to complete its work in 90 days or less.

Although Congress recognized in section 5(c) that EPA may occasionally need more time than 90 days to complete its review of a PMN, such delays are to the be exception, not the rule. Congress added an incentive for EPA to stay on schedule with a mandatory refund in section 5(a)(4):

> If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b), and the Administrator shall not be relieved of any requirement to make such determination.

Similarly, in section 5(a)(3)(C) it actually curtailed the 90-day period where EPA makes a "not likely to present an unreasonable risk" determination by eliminating the previous requirement that PMN submitters wait the full 90 days before commencing non-exempt commercial manufacture.

Moreover, the Senate Report directed EPA to meet the 90-day target whenever it can:

> The Committee notes that ... consistent with current law, the Agency should continue the practice of completing new chemical reviews within 90 days to the maximum extent practicable.[14]

In summary, the growing backlog is a serious concern for all stakeholders. It is also contrary to what Congress intended when it amended TSCA. We offer a number of suggestions below as to how EPA should address the problem.

[14] S. Rep. No. 114-67, 114th Cong., 1st Sess. (June 18, 2015) (Senate Report) at 14-15.

2. Congress Intended the Affirmative Determination Requirement to Promote Transparency

EPA's approach to the obligation to determine that a PMN substance is "not likely to present an unreasonable risk" is based on an interpretation that LCSA mandates a stronger evidentiary base, and a different legal standard, than it used in "dropping" a PMN substance prior to enactment.

EPA should recognize that although the affirmative determination requirement does provide an enhanced basis for review, it did not change the legal standard for review. Importantly, the change serves an important policy objective of increasing transparency.

Congress did not regard the affirmative determination requirement as changing the review criteria for PMNs in a meaningful way. Indeed, the affirmative determination is a mechanism for transparency about the decisions that EPA had been making all along, but without explanation. Additional transparency will give stakeholders other than the PMN submitter insights into EPA's actions and the reasons for those actions. Stakeholders who question those actions will have several opportunities to raise objections, including through comments on a proposed SNUR for the PMN substance; requesting EPA to identify the PMN substance as a high-priority substance under section 6; and filing a section 21 petition or a petition under the Administrative Procedure Act asking EPA to undertake specified activities. Thus, greater transparency provides a check on EPA's actions under the New Chemicals Review Program.

Pre-enactment, whenever EPA decided not to regulate a PMN substance, it offered no explanation of that decision; it simply took no action. In many cases, the decision to "drop" a PMN occurred as early as 15-20 days into the 90-day review period, at the focus meeting. EPA informed the PMN submitter of that decision, but gave no explanation of the reasoning for the decision. The PMN submitter then waited until the 90-day review period expired, after which it could commence non-exempt commercial manufacture of the PMN substance. When EPA published a notice in the Federal Register providing the receipt dates and 90-day due dates for PMNs, it gave the public some sense of that decision, but again, no explanation. In contrast, where EPA did issue a section 5(e) consent order, it provided an explanation of its decision to the PMN submitter (and to the public through FOIA, subject to section 14).

Section 5(a)(3) mandates that EPA make an affirmative determination about each PMN found to be "not likely to present an unreasonable risk." Under section 5(g), EPA must publish in the Federal Register a summary of each determination that a PMN substance is "not likely to present an unreasonable risk," thus giving transparency to those determinations. There was no need to require publication of an explanation of other determinations regarding unreasonable risk, since they would be made in the resulting section 5(e) consent order or rulemaking.

The Senate Report on S. 697 identified the lack of transparency in EPA's reviews of PMNs as a key problem to be addressed:

> Despite the completion of many reviews of new chemicals under section 5, concerns have been raised that it does not require EPA to make an affirmative finding that a new chemical or significant new use is not likely to present an unreasonable risk.[15]

The Senate Report then observed that the requirement in the legislation for an affirmative determination would enhance transparency:

> As with other provisions of S. 697, the section ensures transparency in all EPA decisions on new chemicals or significant new uses.[16]

Nowhere does the legislative history suggest that EPA should change the substantive criteria used for making decisions under section 5.

This added transparency may lead some stakeholders to question EPA's decisions not to restrict particular PMN substances. The purpose of transparency is to allow the public to understand and, at times, question EPA's decisions. Nevertheless, EPA should have been making defensible decisions not to restrict PMN substances during the entire history of the New Chemicals Review Program. Defensible decisions, of course, require sufficient information. The Agency should be making defensible decisions post-enactment as well, without the need for more intense, time-consuming scrutiny. Accordingly, aside from the administrative task of publishing its decisions not to restrict PMN substances, there is no reason for delays in completing PMN reviews for those substances determined to be "not likely to present an unreasonable risk" despite the affirmative determination requirement.

3. EPA Should Broaden Its Interpretation of "Not Likely to Present an Unreasonable Risk"

a. EPA's Interpretation Discounts the Exposure Controls in the PMN

The time-consuming scrutiny that EPA is giving PMNs before finding that they are "not likely to present an unreasonable risk," and the much higher rate at which it is planning to issue section 5(e) consent orders, both mean that EPA has effectively adopted stringent new criteria for a finding that a PMN substance is "not likely to present an unreasonable risk." It has effectively transmuted the concept of risk to one of hazard only, by disregarding exposure controls.

That provision on "not likely to present an unreasonable risk" appears in section 5(a)(3)(C), which provides that EPA may determine:

> that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions

[15] Senate Report at 3.
[16] Senate Report at 14.

> of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

At the December 14 hearing, Maria Doa described EPA's standards for making a "not likely to present an unreasonable risk" determination:

> So the considerations for the "not likely to present," generally, what you will have is there are a couple of different scenarios that we have been looking at. One is that the chemical has low potential for human health and environmental toxicity. It is not both persistent and bioaccumulative. It may be persistent, but not bioaccumulative or vice-versa, and exposure is considered but that consideration of exposure, we do not anticipate that there will be risks. A second type of scenario is where the toxicity is higher, but the information on all the exposure scenarios that we have considered do not present unreasonable risk. And this includes foreseen uses. The third scenario would be you have the potential for higher toxicity, but the exposure is self-limiting, such as physical/chemical property, something that would impede the potential for exposure.[17]

Those appear to be the only scenarios that EPA would accept as establishing that a PMN substance is "not likely to present an unreasonable risk." While those scenarios are unobjectionable, they exclude other scenarios that should also qualify as "not likely to present and unreasonable risk."

For example, in many cases, there may be potential for toxicity, but the exposure controls in the PMN would be sufficient to prevent exposure, resulting in low risk. EPA does not appear to regard this scenario as sufficient to establish "not likely to present an unreasonable risk." ACC members and speakers at the December 14 meeting indicated that EPA is insisting on section 5(e) consent orders that would require the PMN submitter to implement the controls it described in its PMN.

EPA may be discounting the exposure controls described in PMNs because they are not enforceable through a section 5(e) consent order. It is also requiring section 5(e) consent orders where those enforcement controls would, if implemented, be sufficient to address concerns from the activities of the PMN submitter and its direct customers, but would not necessarily be followed by other manufacturers of the PMN substance after it is added to the Inventory and their customers. This puts the PMN submitter in an impossible situation, since it cannot commit other manufacturers to use particular exposure controls. The end result is that EPA is largely disregarding the exposure side of the risk equation, and requiring section 5(e) consent orders based primarily on concerns about hazard.

This is not what Congress had in mind with respect to the term "unreasonable risk" and its variations in the statute. Congress wanted EPA to consider exposure, and exposure controls, as well as hazard – the elements that together constitute an enhanced level of review for PMNs. By insisting in many cases that any exposure controls be enforced by a section 5(e) consent order, EPA is veering dangerously into a hazard-based regulatory system under section 5.

---

[17] Transcript at 6.

b. EPA Should Rely on the Exposure Controls in the PMN

For the first 35 years of the New Chemicals Review Program, EPA was usually satisfied that a PMN submitter would indeed implement the controls that it had described. Where implementation of the described controls would preclude a finding of "may present an unreasonable risk," the possibility that a PMN submitter would not implement the controls was not sufficient to support a section 5(e) consent order based on a finding of "may present an unreasonable risk." Now, although Congress did not mandate such a change in the legislation, EPA has apparently – and without explanation – changed its approach.

The explanation may be that EPA considers that it is "reasonably foreseeable" that the PMN submitter would not implement those controls, and it feels that that possibility precludes a determination that a PMN substance is "not likely to present an unreasonable risk."

According to Merriam-Webster, definitions for "likely" include "having a high probability of occurring or being true" and "very probable."[18] In contrast, "possible" implies a much lower probability, with a definition of "being within the limits of ability, capacity, or realization."[19]

In other words, to find that a PMN substance is "not likely to present an unreasonable risk," EPA must find that there is not a "high probability" of the risk occurring, or that such a risk is not "very probable." Often, a PMN submitter describes exposure controls in its PMN that it intends to implement prior to commercialization and which, if implemented, would preclude a "may present an unreasonable risk" determination. In that case, it is certainly not "highly probable" or "very probable" that the PMN submitter will not implement those controls, unless EPA has clear evidence to the contrary. EPA should find there that the PMN substance is "not likely to present an unreasonable risk."

At one point during the Congressional consideration of the LCSA, some stakeholders advocated for a different standard: "likely not to present an unreasonable risk." Their sense was that it would be more difficult for EPA to make that finding, and accordingly there would be more section 5(e) consent orders. Under that language, arguably EPA would have had to find that it was likely, i.e., there was a "high probability" that the PMN substance would not present an unreasonable risk.

That wording was not accepted, however. The language that was accepted, "not likely to present an unreasonable risk," implies the absence of sufficient evidence to establish that occurrence of an unreasonable risk has a "high probability" or is "very probable." Thus, EPA should not regard "not likely to present an unreasonable risk" as though it had that more restrictive wording.

[18] See https://www.merriam-webster.com/dictionary/likely.
[19] See https://www.merriam-webster.com/dictionary/possible.

4. EPA Should Recognize That the "Not Likely to Present an Unreasonable Risk" Standard Differs Little From What Applied Prior to Enactment

When EPA decides that a PMN substance is "not likely to present an unreasonable risk," it is effectively deciding that a section 5(e) consent order (or a rule under section 5(f) based on a finding that the substance "presents an unreasonable risk") is not appropriate.

It is not necessary for EPA to define new scenarios that will allow it to make a "not likely to present an unreasonable risk" determination. That standard is essentially the same as that which EPA used in deciding to "drop" PMNs prior to enactment. That standard was that the PMN substance did not meet the standards for issuance of a section 5(e) consent order (or a rule under section 5(f) based on a finding that the PMN substance "presents an unreasonable risk").

The LCSA did amend the relevant language for issuing section 5(e) consent orders. Prior to June 22, the relevant language was that in section 5(e)(1)(A), where EPA issued consent orders based on the following:

> (i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and
>
> (ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment ....

Thus, the key standard was, and remains, "may present an unreasonable risk." In about 90% of cases, EPA was able to find that a PMN substance did not meet that standard, and it allowed commercialization without a section 5(e) consent order.

Under section 5(a)(3)(B)(i) of TSCA as amended, the "insufficient information" provision is now an independent basis for a section 5(e) consent order. Otherwise, section 5(a)(3)(B)(ii)(I) is now the key provision, and it is clearly modeled on section 5(e)(1)(A)(ii)(I):

> (ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator ....

"May present an unreasonable risk" has not changed. Only the following changes have been made:

- The reasonableness of the risk is to be determined "without consideration of costs or other nonrisk factors"

- The determination must consider the risks to "a potentially exposed or susceptible subpopulation identified as relevant by the Administrator"

These factors are also included in EPA determinations that a PMN substance is "not likely to present an unreasonable risk" under section 5(a)(3)(C).

As amended, section 5 now requires EPA to make its "may present an unreasonable risk" determinations on the basis of risks to health or the environment, without considering economic or other factors. ACC understands that such factors were never a significant part of EPA's assessment of PMNs during the 35 years of the New Chemicals Review Program prior to June 22. Those factors were critical in determinations under section 6 of whether a chemical such as asbestos "presents an unreasonable risk," but not under section 5.[20]

EPA now has an express requirement to consider the risks to workers or other potentially exposed or susceptible subpopulations. This requirement codifies the practice EPA had certainly adopted under TSCA before amendment. It would be startling to learn that EPA had not been doing that throughout the New Chemicals Review Program prior to the LCSA. Indeed, many section 5(e) consent orders issued prior to LCSA contain provisions addressing workplace protections or effectively prohibiting distribution to consumers. Likewise, EPA must have been considering potential exposures to children in the past, and it would be similarly startling if EPA had not done that in the past. Congress' decision to articulate the considerations that EPA has been using all along should not trigger a change to EPA's decision-making about "may present an unreasonable risk."

In short, nothing in new section 5(a)(3)(B)(ii)(I) justifies the abrupt and dramatic increase in the number of section 5(e) consent orders now under consideration by EPA, or EPA's corresponding refusal to allow commercialization without a consent order where, prior to enactment, it would have allowed such commercialization.

5. EPA Should Revise Its Interpretation of the Phrase "Reasonably Foreseen"

EPA regards the "reasonably foreseen" phrase in the definition of "conditions of use" (as that term is used in amended section 5), as a mandate for a much-expanded scope of review of a PMN substance. That expanded scope of review is apparently leading to many more section 5(e) consent orders than was the case pre-enactment. All those section 5(e) consent orders are contributing substantially to the backlog of PMN reviews. EPA is misapplying that term in its review of PMNs.

a. EPA Erroneously Considers "Reasonably Foreseen" to Expand the Scope of PMN Review

The term "reasonably foreseen" appears in the definition of the term "conditions of use" in section 3(4), which provides:

[20] In his congressional testimony on TSCA legislation, Assistant Administrator Jim Jones lamented the requirement in section 6 to balance costs and benefits. In contrast, he had few, if any, criticisms of section 5.

> The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

At the December 14 hearing, Jeff Morris commented on the phrase "reasonably foreseen":

> Also the new element to the law is that, as we have interpreted the statute, the conditions of use around which we evaluate a new substance include not only the use of identified in the premanufacture notice, but also any reasonably foreseen uses.[21]

Maria Doa even provided an example of where EPA would issue a section 5(e) consent order based solely on the uses which someone other than the PMN submitter might use in manufacturing the substance after it is added to the Inventory:

> The PMN substance is made [by the PMN submitter] in a way in which there is no free reactive moiety in the chemical substance. However, once it's on the inventory, it can be made in a way such that there will be this reactive moiety in the chemical substance. And from what we know about the chemical and the reactive moiety, we know a lot about the foreseen uses and there will be a potential for both worker and consumer exposure from the uses of these chemicals. So the chemical here may present an unreasonable risk to health based on the foreseeable uses.[22]

EPA's reasoning appears to be that "reasonably foreseen" requires it to consider conditions of use not intended by the PMN submitter nor reasonably to be anticipated from the conditions of use that are described in the PMN. Instead, it apparently believes that it is now required to consider conditions of use that reasonably may be foreseen from activities by persons other than the PMN submitter and its direct customers,[23] such as other manufacturers and their downstream customers, once the PMN substance is added to the Inventory.

b. Section 5(e) Consent Orders Based on Foreseen Uses by Third Parties Serve No Function

EPA's reasoning is flawed, as explained below. But before critiquing the reasoning, ACC must point out a practical problem for which EPA appears to have no response: a section 5(e) consent order issued to a PMN submitter based on foreseen uses by persons other than the PMN submitter and its direct customers has no regulatory effect – thus, it serves no purpose.

Consider the example presented in the preceding section. The PMN submitter there proposes to manufacture the PMN substance in a manner that does not create a free reactive moiety, the

---

[21] Transcript at 2.
[22] Transcript at 9.
[23] Only EPA and the PMN submitter sign a section 5(e) consent order, so the PMN submitter's direct customers are not signatories. Some consent orders contain provisions prohibiting the PMN submitter from distributing the PMN substance to its direct customers who do not agree in writing to comply with certain of the consent order provisions. Thus, the direct customers may become contractually bound to comply with the specified provisions.

subject of EPA's concern. A section 5(e) consent order prohibiting the PMN submitter from manufacturing the substance in a manner that does create the free reactive moiety would have no practical effect, since the PMN submitter was not going to do that anyway. In addition, a section 5(e) consent order would have no effect on subsequent manufacturers who might begin to manufacture the substance after it is added to the Inventory in a manner that does create the free reactive moiety. They are the persons whom EPA wants to restrict. Yet they are not signatories to the consent order. They remain unaffected by it. EPA must still promulgate a SNUR in order to restrict their manner of manufacture. EPA has accomplished nothing useful by prohibiting the PMN submitter from doing what it had no intention of doing. However, it has delayed completion of the PMN review process by months while developing, negotiating, and then issuing the consent order.

ACC understands from its members that many of the backlogged PMN substances are facing section 5(e) consent orders due solely to uses that EPA foresees on the part of persons other than the PMN submitter and its direct customers. The futility of EPA's insistence on section 5(e) consent orders in this situation is causing major disruptions of the New Chemicals Review Program. It is certain that Congress intended no such change in the program. In legal parlance, such orders may be regarded as "arbitrary or capricious" since they do not effectuate any protection of health or the environment.

c. "Reasonably Foreseen" Does Not Appear in Section 5(a)(3)(B), Pertaining to Determinations to Issue Section 5(e) Consent Orders

Significantly, the phrase "conditions of use" (with its "reasonably foreseen" language) is not applicable to determinations triggering the issuance of section 5(e) consent orders as provided in section 5(a)(3)(B).

That provision directs EPA to issue section 5(e) consent orders if it makes certain determinations.[24] That provision identifies three determinations that can trigger a section 5(e) consent order:

---

[24] For reference, section 5(a)(3) provides:

> REVIEW AND DETERMINATION.—Within the applicable review period, subject to section 18, the Administrator shall review such notice and determine—
>
> (A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);
>
> (B) that—
>
> > (i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or
> >
> > (ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

- The first, under section 5(a)(3)(B)(i), is that there is "insufficient information" available to make a reasoned evaluation. That provision does not include the phrase "conditions of use."[25]

- The second, under section 5(a)(3)(B)(ii)(I), is that the PMN substance "may present an unreasonable risk." That provision does not include the phrase "conditions of use" either, although its restatement in section 5(e)(1)(A)(II) does.[26]

- The third, under section 5(a)(3)(B)(ii)(II), is that the PMN substance will be produced in "substantial quantities" and that there will be "substantial or significant" exposure to the PMN substance. Like the other determinations triggering a section 5(e) consent order, that provision does not contain the phrase "conditions of use."[27]

Accordingly, EPA should not apply any interpretation of "reasonably foreseen" to a determination to issue a section 5(e) consent order.

The phrase "conditions of use" appears twice in section 5(a)(3). It is part of section 5(a)(3)(A), which directs EPA to conduct rulemaking if it determines that a PMN substance presents an unreasonable risk. EPA is likely to make that determination rarely, if ever. Thus, that provision may be disregarded for present purposes.

The other place "conditions of use" appears is in section 5(a)(3)(C), where EPA determines that a PMN substance is "not likely to present an unreasonable risk" under the "conditions of use." It is in this context that EPA's interpretation of "reasonably foreseen" should be examined.

d. Congress Intended That "Reasonably Foreseen" as Used in Section 5 Refers to Conditions of Use Related to the PMN Itself, Not to Those of Third Parties

EPA has erred in concluding that, in the PMN context, "reasonably foreseen" can refer to persons other than the PMN submitter and its direct customers. It has erred in construing that

---

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

[25] Similarly, where that provision is restated in section 5(e)(1)(A)(i) that restatement does not include the term "conditions of use."

[26] The inconsistency between the two provisions creates ambiguity indicating that Congress did not consider that "conditions of use" be a critical factor in deciding whether to issue a section 5(e) consent order.

[27] Where that provision is restated in section 5(e)(1)(A)(ii)(II), that restatement does not include the term "conditions of use."

phrase to mean that it must speculate about the conditions of use that may occur once a PMN substance is added to the Inventory and anyone can manufacture or process it.

On the contrary, the Senate Report emphasized that "reasonably anticipated" (a clear reference to "reasonably foreseen") exposures should be considered "consistent with existing law" and that the PMN submitter (who has no knowledge of the conditions of use of anyone besides itself and its direct customers) must submit the information on those exposures:

> Consistent with existing law, the PMN submitter must provide EPA all available relevant information, including information on the intended conditions of use and reasonably anticipated exposures. The Committee intends that the review of the PMN should be conducted in that context.[28]

It is clear from this statement that Congress expected that the current PMN regulations would govern the information that EPA is to consider in reviewing PMNs. Those regulations require a PMN submitter to provide exposure-related information both for sites controlled by the submitter and for sites not controlled by the submitter, including the "categories of use."[29] Yet EPA has never interpreted those long-standing regulations to require information about uses by other manufacturers of the PMN substance after it is added to the Inventory, as EPA is now demanding. In LCSA, Congress considered that "reasonably anticipated exposures" would be those resulting from the activities of the PMN submitter and, possibly, those of its direct customers. Congress did not require speculation about what might occur once third parties can manufacture the PMN substance following its addition to the Inventory.

What does "reasonably foreseen" mean in the context of section 5(a)(3)(C)? As noted above, "conditions of use" refers to "the circumstances … under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The phrase "reasonably foreseen" thus modifies "intended" and "known."

In H.R. 2576 as passed by the House in 2015, the phrase was "intended conditions of use."[30] Similarly, in the original bipartisan bill introduced by Senator Lautenberg and Senator Vitter and others in 2013, S. 1009, the term was "intended conditions of use."[31] That was later changed to "conditions of use" in the subsequent Senate bill and the final legislation in recognition that there could be reasonably foreseeable uses that are neither intended nor known. Nevertheless, the emphasis remained on "intended, known" conditions of use (those described in the PMN) and any conditions of use which may be "reasonably foreseen" from those uses.

---

[28] Senate Report at 15.
[29] 40 C.F.R. § 720.45(f)-(h).
[30] H.R. 2576, 114th Cong., 1st Sess. (July 28, 2015), § 3 ("The term 'intended conditions of use' means the circumstances under which a chemical substance is intended, known, or reasonably foreseeable to be manufactured, processed, distributed in commerce, used, and disposed of.").
[31] S. 1009, 113th Cong., 1st Sess. (May 22, 2013), § 3. Even that version included the concept of reasonable foreseeability. The definition of "intended conditions of use" read, "The term 'intended conditions of use' means the circumstances under which a chemical substance is intended or reasonably anticipated to be manufactured, processed, distributed in commerce, used, and disposed of."

Under section 6, where many people may use a chemical substance, it may be appropriate to consider a broad range of reasonably foreseeable occurrences. As explained by the House Report on H.R. 2576, which did not propose to amend section 5:

> The Committee expects that the Agency will generally interpret this [phrase, "intended conditions of use"] to mean intended by the manufacturer, known by the manufacturer or the public, or reasonably foreseeable by the manufacturer or the Administrator.[32]

Under section 5(a)(1), which focuses just on PMNs, however, it is only appropriate to consider just what is reasonably foreseeable from the intended uses defined in the PMN, and which relate to the PMN submitter and its direct customers.

Insight should come from the Consumer Product Safety Act. Case law has established that the risks to be evaluated under that statute include "reasonably foreseeable misuse."[33] Similarly, in tort law, the manufacturer must warn against "reasonably foreseeable misuse."[34] For PMNs substances, spills by the PMN submitter or its direct customers may be "reasonably foreseen" misuse that EPA should consider.

Thus, in the PMN context, EPA may consider the potential, "reasonably foreseen," misuse by the PMN submitter or its direct customers, such as the potential for spills. For example, where the PMN indicates that the PMN submitter or its direct customers will handle the PMN substance in open (rather than closed) processes, EPA may reasonably expect that spills may occasionally occur. EPA should evaluate whether the potential for spills from the intended uses prevents EPA from making a "not likely to present an unreasonable risk" finding under section 5(a)(3)(C).

However, in the PMN context, it is not reasonable for EPA to consider whether spills or other reasonably foreseeable uses by persons other than the PMN submitter and its direct customers after the PMN substance is added to the Inventory prevent EPA from making a "not likely to present an unreasonable risk" finding under section 5(a)(3)(C).

This is apparent from the text of section 5(a)(2)(D). One of the enumerated factors that EPA must consider before promulgating a SNUR is:

> the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

That factor well captures the idea behind the term "conditions of use" as applied to persons other than the PMN submitter and its direct customers. "Reasonably anticipated" is essentially

---

[32] H.R. Rep. No. 114-176 (June 23, 2015), at 22.

[33] See, e.g., *Southland Mower Co. v. CPSC*, 619 F.2d 499 (5th Cir. 1980) ("Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk. *Aqua Slide*, 569 F.2d at 841. See S. Rep.No.92-749, 92d Cong., 2d Sess. 14, 92 Cong. Rec. 36198 (1972) (remarks of Sen. Moss) (risk of injury "associated with" consumer products, 15 U.S.C. § 2052(a)(3), to be regulated by CPSC includes risks of injury resulting from "exposure to or reasonably foreseeable misuse of a consumer product.").

[34] See, e.g., *Stults v. International Flavors & Fragrances, Inc.*, 31 F. Supp. 3d 1015 (N.D. Iowa 2014) (citing cases).

synonymous with "reasonably foreseen."[35] Unlike EPA's review of PMNs, however, a SNUR is not limited to the "manner and methods" of the PMN submitter and its direct customers. Instead, in the SNUR context, EPA should consider (and apparently has, since the inception of the New Chemicals Review Program) the "manner and methods" of anyone who may manufacture, process, distribute, or dispose of the chemical substance.

Thus, Congress effectively directed EPA in promulgating SNURs to consider the "reasonably foreseen" conditions of use of persons other than, or in addition to, the PMN submitter and its direct customers. With that understanding, it is unsupportable for EPA to conclude that it must consider exactly the same thing in evaluating PMNs, or that it must issue section 5(e) consent orders where a SNUR would be appropriate based on that factor.

e. Nothing in the Legislative History Indicates that "Conditions of Use" Alters EPA's Substantive Review of PMNs

As noted earlier, ACC agrees that LCSA enhanced EPA's PMN review authority, particularly to assure that sufficient information existed to make a determination whether a new chemical poses an unreasonable risk or not. Notably, however, Congress provided no indication that the term "conditions of use" should be interpreted to change the review standard for new chemicals. If Congress had intended the term "conditions of use" to substantially alter EPA's evaluation of PMNs, it surely would have indicated that. Congress expressed no concern with EPA's evaluation of PMNs or an intention that EPA should change its approach to that evaluation.

For example, Congress did not express concern that EPA had been allowing unsafe chemical substances to enter the marketplace without restriction. Indeed, EPA's historical implementation of section 5 was widely praised by witnesses at both the Senate and the House hearings. Several stakeholders urged Congress not to amend section 5 at all, since that was one part of TSCA that was working extremely well. EPA itself believes that section 5 as implemented pre-enactment was very effective at keeping unsafe new chemical substances off the market.[36]

The House bill, H.R. 2576, reflected that viewpoint. As passed by the House of Representatives in 2015, it had no provision amending section 5.[37]

The Senate bill, S. 697, did include language amending section 5. However, the Senate Report on that bill had no criticism of EPA decisions not to restrict PMN substances, other than the fact that EPA provided no explanation of those decisions:

---

[35] "Foreseeability" and related terms are commonly defined as "reasonably anticipated." See, e.g., West's Encyclopedia of American Law, edition 2 (2008) ("Foreseeability" means "The facility to perceive, know in advance, or reasonably anticipate that damage or injury will probably ensue from acts or omissions.").

[36] See, e.g., EPA, Fiscal Year 2017, Justification of Appropriation (Feb. 2016), https://www.epa.gov/sites/production/files/2016-02/documents/fy17-congressional-justification.pdf, at 517 (consistently high marks on EPA's own metric, "Percent of new chemicals or organisms introduced into commerce that do not pose unreasonable risks to workers, consumers, or the environment").

[37] H.R. 2576 (as passed by the House on June 23, 2015 by a vote of 398-1).

> Despite the completion of many reviews of new chemicals under section 5, concerns have been raised that it does not require EPA to make an affirmative finding that a new chemical or significant new use is not likely to present an unreasonable risk.[38]

It is not clear that Congress even gave much thought to the application of the term "conditions of use" to PMN reviews. This may be reflected in the omission of references to the term in section 5(a)(3)(B), as discussed above. The Senate Report focused instead on use of the term in section 6:

> "Conditions of Use" is a term used throughout S. 697 to describe the context in which EPA will apply the safety standard in safety assessments and determinations. The term means the "intended, known, or reasonably foreseeable circumstances" under which a chemical substance is manufactured, processed, distributed in commerce, used or disposed of. The term is not intended to include "intentional misuse" of chemicals.[39]

The phrase "safety assessments and determinations" corresponds to the phrase "risk evaluations" in the final legislation. Thus, Congress saw the term as primarily intended to affect risk evaluations under section 6.[40] There is no evidence that it gave any consideration to how referring to "conditions of use" in section 5 might affect EPA's review of PMNs. Certainly, Congress expressed no intention to upend the New Chemicals Review Program by mandating a much more expansive scope to PMN reviews.

6. EPA Should Pursue Alternatives to Section 5(e) Consent Orders

a. EPA Should Discuss Options with the PMN Submitter Immediately After the Focus Meeting

With EPA setting a very challenging standard for "not likely to present an unreasonable risk," EPA's default approach has been to presume that a section 5(e) consent order will be necessary in most cases. This is an unnecessarily narrow approach that is contributing to the backlog.

One practical option available to EPA is to discuss its initial concerns with the PMN submitter immediately after the focus meeting, which typically held on Days 15-20 of the PMN review period. This discussion may identify paths to avoid the need for a section 5(e) consent order.

In the discussion, EPA should explain to the PMN submitter its initial concerns. This may allow the PMN submitter to respond to questions underlying those initial concerns; to correct misimpressions; and to offer information or changes to exposure controls which may effectively resolve those initial concerns.

---

[38] Senate Report at 3.
[39] Senate Report at 7.
[40] See also Cong. Rec. S3519 (June 7, 2016) (remarks of Sen. Vitter responding to a question on how "conditions of use" should be applied by EPA in risk evaluations under section 6).

For example, the PMN submitter may not have recognized that EPA may regard "disposal" of wastes to include disposal to a regular landfill, whereas the PMN submitter had planned to dispose of wastes only in a hazardous waste landfill. Alternatively, the PMN submitter could offer to amend its planned practices to send wastes to a hazardous waste landfill.

The discussion could identify information that would help EPA resolve its concerns. This is particularly useful where EPA may be considering a section 5(e) consent order based on "insufficient information." While PMN submitters are required to submit all available health and safety studies, a concern about hydrolysis, for example, may trigger a more detailed search that uncovers an existing hydrolysis study (e.g., as submitted to a foreign regulatory body). Alternatively, the PMN submitter may volunteer to conduct a hydrolysis study.

The PMN submitter may be able to refer EPA to previous evaluations of the PMN substance by EPA's foreign counterparts, e.g., in China or under REACH. Although those evaluations would not be binding on EPA, they may be influential.

Such discussions can develop a variety of alternatives to a section 5(e) consent order. They should take place as early in the review period as possible, preferably immediately after the focus meeting.

b. EPA Should Encourage Use of the "Binding Option" Without Requiring a Section 5(e) Consent Order, or by Using an Expedited Consent Order Process

Where EPA would otherwise plan to issue a consent order based on concern that the PMN submitter would not implement the described controls, EPA should simply ask the submitter to amend its PMN to select the "binding option" for the relevant controls. In that way, the PMN submitter will commit to implement those controls, and EPA can proceed to make a determination of "not likely to present an unreasonable risk."

Heretofore, EPA has considered selection of a "binding option" to be an invitation to agree to a section 5(e) consent order, because it did not regard a "binding option" to be binding in the absence of such an order.[41] However, EPA should regard selection of a "binding option" to be a commitment by the PMN submitter. Page 2 of the PMN form requires the submitter to make the following certification:

---

[41] See EPA PMN Instruction Manual (2015) at 16-17 ("Indicating a willingness to be bound by the terms of your PMN notice does not by itself prohibit the submitter from deviating after the end of the review from the information (except chemical identity) which had been reported in EPA Form 7710-25 (unless the submitter and the Agency enter into a binding TSCA section 5(e) Consent Order), but it does provide a starting point for discussions between EPA and the submitter. A checked box can help EPA and the PMN submitter negotiate efficiently in the development of 5(e) consent orders and help the Agency promulgate Significant New Use Rules (SNURs) for those new chemical substances that the Agency determines may present an unreasonable risk if certain control actions are not implemented. The purpose of the binding box is to reduce delays that can slow the development of consent orders absent such prior agreement."). ACC notes, however, that a section 5(e) consent order need not be necessary in many cases involving binding options.

> I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate ....
>
> Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

That certification may include selection of a "binding option" for particular controls. EPA has significant remedies if the PMN submitter makes a "binding option" selection and does not meet that commitment, including criminal prosecution for knowing and willful misrepresentation.

PMN submitters are often reluctant to select the "binding option" because of concern that in the future alternative controls may become available that provide equal or greater protection to health and the environment, yet they would be unable to make changes to controls for which "binding option" was selected. EPA could facilitate selection of "binding option" by revising the PMN Manual to explain that a "binding option" is a commitment of the PMN submitter for which it may be held accountable, and to indicate that if, after commercialization, the PMN submitter would prefer to change controls, it may simply send EPA a letter explaining the basis for the change and requesting EPA's approval. EPA could respond by letter approving the change, disapproving it, or suggesting alternative approaches. In this way, the "binding option" process could be made more effective and could be a much more efficient approach than requiring a section 5(e) consent order.

Alternatively, if EPA does insist on a section 5(e) consent order to ensure that a "binding option" selection is indeed binding, it could revise the current cumbersome process with an expedited one. A section 5(e) consent order in this context could be quite brief, a few pages at most, committing the PMN submitter to use the exposure controls for which it has selected a "binding option." Such consent orders could also have an expedited process for amendments based on a satisfactory showing by the PMN submitter that different controls would provide equal or greater protection. ACC believes, however, that superimposing a section 5(e) order on top of a binding option commitment is substantially more cumbersome than needed to provide EPA compliance assurance. Again, this result would be in sharp distinction to pre-LCSA practice.

c. EPA Should Resume Issuance of Non-Section 5(e) SNURs

EPA's SNUR authority in section 5(a)(2) complements its PMN authority in section 5(a)(1). Congress recognized this by directing in section 5(f)(4) that after issuing a section 5(e) consent order for a PMN substance, EPA must, within 90 days, consider promulgating a SNUR for that substance. EPA has an expedited process for issuing such section 5(e) SNURs in 40 C.F.R. § 721.160.

Sometimes the uses described in a PMN do not raise a substantial concern, but potential uses by others after the PMN substance is added to the Inventory do. Historically, EPA has used a SNUR to address those concerns. In those contexts it has not also issued a section 5(e) consent order, since the PMN submitter's actions did not raise those concerns, and a section 5(e) consent order would have done nothing to redress those concerns. EPA has an expedited process for issuing such non-section 5(e) SNURs in 40 C.F.R. § 721.170.

Since enactment, EPA has halted issuance of non-section 5(e) SNURs. Instead, in every instance where previously it would have issued a non-section 5(e) SNUR, it is planning to issue a section 5(e) consent order to be followed by a SNUR. This abandonment of the non-section 5(e) SNUR mechanism has contributed to the backlog by driving EPA to develop, negotiate, and issue section 5(e) consent orders that previously would have been unnecessary.

Non-section 5(e) SNURs serve an important function. EPA adopted the expedited process for promulgating non-section 5(e) SNURs that appears in 40 C.F.R. § 721.170 because "a non-section 5(e) SNUR may be the least burdensome regulatory alternative for the Agency to pursue."[42] In doing so, it advanced the policies of section 2(b)(3), that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." As explained in the 1995 preamble adopting that regulation:

> A non-section 5(e) SNUR is typically appropriate for PMNs on chemical substances expected to be toxic but where the PMN indicates the submitter's intention to limit activities, implement control measures, or otherwise adequately mitigate human exposures and environmental releases. **Activities described in such PMNs may not present an unreasonable risk of injury** to human health or the environment so as to warrant the issuance of an Order under section 5(e) of TSCA [followed by promulgation of a section 5(e) SNUR], but deviations from the described activities may present an unreasonable risk warranting the imposition of regulatory controls via a section 5(e) Order. In those cases, **a non-section 5(e) SNUR may be the least burdensome regulatory alternative** for the Agency to pursue, as it will allow the PMN submitter to proceed with planned activities while requiring notification to, and review by, EPA for activities which have not been reviewed.[43]

EPA concluded that the use of non-section 5(e) SNURs would "eliminate unnecessary section 5(e) Orders" then being issued to PMN submitters:

> Thus, this rule amendment is intended to eliminate unnecessary section 5(e) Orders and should not itself increase the number of new chemical substances regulated by EPA via SNURs under section 5 of TSCA. Rather, substances that would formerly have been regulated by 5(e)-SNURs may now be regulated by non-section 5(e) SNURs.[44]

EPA's new refusal to promulgate non-section 5(e) SNURs returns the Agency to the exact situation that the adoption of § 721.170 in 1995 was designed to avoid: issuance of unnecessary section 5(e) consent orders.

---

[42] See footnote 43.
[43] 60 Fed. Reg. 16311, 16313 (Mar. 29, 1995) (emphasis added).
[44] 60 Fed. Reg. at 16313.

Unnecessary section 5(e) consent orders hurt all parties. EPA is burdened with the additional work of drafting, negotiating, and adopting those unnecessary orders. PMN submitters are burdened by the delay of waiting for EPA to draft the orders, negotiating them with EPA, and then waiting for EPA to issue the orders. The public and the environment are burdened from the same delay, as innovative technology and greener chemicals are kept from the market for sometimes extended periods.

If EPA continues to refuse to promulgate non-section 5(e) SNURs, at a minimum it should explain why section 5(e) consent orders are not "unnecessary," and how the new policy advances the policies of section 2(b)(3).

Yet that is the situation EPA is embracing by declining to issue any more non-section 5(e) SNURs. EPA has many demands on its scarce resources with implementation of TSCA as amended. It should not needlessly divert resources to issue unnecessary section 5(e) consent orders.

The futility of issuing "unnecessary" section 5(e) consent orders is manifest. Such orders only apply to PMN submitters and, perhaps, their direct customers. Whereas a non-section 5(e) SNUR would efficiently address concerns raised by persons other than the PMN submitter and its direct customers, a section 5(e) consent order in that context would have no helpful effect at all.

EPA has not explained why it has abandoned the non-section 5(e) SNUR mechanism. Presumably, it is because its interpretation of "reasonably foreseen" has convinced it that it must issue a section 5(e) consent order even when the concerns that it foresees are not raised by the PMN itself, but instead by others after the PMN substance is added to the Inventory. As discussed above, EPA is misinterpreting "reasonably foreseen" in the PMN context. It should recognize that issuing a section 5(e) consent order in this context is meaningless and only slows down the review process, to the detriment of all stakeholders.

CONCLUSION

ACC agrees that the LCSA made some important changes to section 5 of TSCA. EPA now has a mandate to ensure that sufficient information exists to make a decision. EPA must explicitly account for potential exposures to humans, codifying EPA's past practice. EPA must be more transparent about how it reaches decisions in the New Chemicals Program. But the changes in section 5 were clearly not intended to have a significant negative impact on the operation of the program as a whole. EPA's implementation of its new section 5 authority has created a large and growing backlog of PMNs awaiting final determinations. The problem is getting worse, not better. EPA should take the following steps to redress the problem:

- It should acknowledge that the current delays are not a temporary phenomenon that will pass as EPA works through the backlog of PMNs for which it "reset" their review periods. Instead, it should take responsibility for the current situation and take steps to redress it.

- It should recognize that the affirmative determination requirement for PMN substances found to be "not likely to present an unreasonable risk" does not affect the substantive standard for review..

- It should acknowledge that the standard of "not likely to present an unreasonable risk" is not significantly different from the standard it used pre-enactment to determine that no section 5(e) consent order or other restriction was necessary.

- It should consider exposure controls, and ensure that PMN decisions are made on the basis of risk, not hazards.

- It should stop requiring a section 5(e) consent order in situations where the PMN submitter's uses described in the PMN would adequately control the risk if implemented, unless EPA has a clear basis for believing that they are unlikely to be implemented.

- It should stop requiring a section 5(e) consent order in situations where uses described in the PMN do not create a substantial concern, but uses by others after the PMN substance is added to the Inventory do create such a concern.

- It should meet with PMN submitters immediately after the focus meeting to discuss its initial concerns and address options for resolving those concerns, options that may include but would not be limited to a section 5(e) consent order.

- It should encourage PMN submitters to select the "binding option" for critical exposure controls, then rely on that commitment without requiring a section 5(e) consent order. It should provide a simple mechanism for approval of future changes to those controls if needed.

It should resume issuing non-section 5(e) SNURs.

APPENDIX 1

ACC Member Experiences Under the New Chemicals Review Program Since Enactment

Requesting Information Beyond the Scope of the PMN

- Company A received multiple onerous requests for more information that, in some cases, appear to have minimal technical value. Some requests were for downstream information that may be unavailable due to CBI protections.

  For example, EPA requested information on the potential for the new substance to contaminate wastewater effluent during processing and monitoring of these streams. It is difficult to understand the rationale for this request based on following:

  - The new substance is a solid material;
  - The new substance is hydrophobic;
  - Based on similar analogues, the new substance is expected to be immiscible in water;
  - Water is not used during the manufacturing process.

- Company B received a request for downstream processing information of the PMN substance. EPA has essentially requested completion of PMN pages 10/10A concerning industrial sites controlled by others. Since this is a new chemical substance, the downstream customer has not purchased the substance for commercial use and has not fully developed and optimized its process; therefore, the data EPA is requesting does not exist or is not attainable, and proprietary business concerns may limit the PMN submitter's access to such data. EPA does not appear to be considering that:

  - The new substance is a chemical intermediate and is intended to be completely consumed in downstream derivations and synthesis;
  - Company B cannot provide data on downstream user's processing efficiency to consume all of new substance;
  - Company B cannot provide data on downstream user's processing waste streams and clean-outs to ensure new substance is not in these effluent streams;
  - These requests could greatly extend the lead time necessary for filing a PMN if confidentiality agreements are required with downstream users to attain such information.

- Company C received a request for sales price data for EPA's economic analysis. It is not clear why this was requested, but it may be used to set a threshold volume calculation in the section 5(e) consent order. It appears that EPA may be trying to determine volume based on the cost of the studies it is requiring in a consent order. Company C has yet to receive a request in writing from EPA and Company C has not supplied EPA with this information to date.

Policy Shifts without Notice

- Company D submitted an LVE in which the precursors are imported and are PBTs. This substance has a very small use in the U.S. and that use is very controlled. It is then shipped out of the country. For years, Company D has been in this business and has never had a problem with any similar LVEs. The previous LVEs had always been approved. This is the first time in Company D's experience that an LVE has been denied. This is a huge problem for this chemistry. It has a short development cycle of 12-16 months, so it is almost impossible to meet the PMN requirements. The business line impacted by EPA's change in approach threatens a $10 million business that employs 45+ people. Company D is considering whether to move the business overseas.

PMNs Dropped Prior to Enactment Subject to New Review

- Company E has a PMN that has been under review for more than 6 months. It was dropped before enactment of the LCSA. After enactment, EPA re-reviewed the PMN and said it has identified a high concentration of concern (COC) for ecotoxicity. Before submission of its PMN, Company E engaged the Consortium for Environmental Risk Management (CERM) – a Sustainable Futures Program (SFP) partner – to conduct a risk assessment consistent with the a SFP's screening tools. The results were included in the PMN. EPA notified Company E that it received different results than those in the PMN, i.e., a COC 100 times greater than that shown in the risk assessment results provided in the PMN. The EPA ecotoxicity review group apparently decided without notice to industry or EPA's SFP partners that it will no longer accept nitrogen mitigation in association with ecotoxicity assessments. Therefore, Company E wasted resources on the risk assessment performed ahead of submitting the PMN. EPA is now requiring a 90-day inhalation test with a 60-day hold before beginning the test (5-month waiting period).

- Company F submitted a PMN to EPA before enactment of the LCSA, but EPA dropped the PMN from further review before enactment. The business unit was set to launch and had to pull back (wasting resources) because after enactment of the LCSA, EPA notified Company F that its PMN review period had been reset (effectively, extended 90 days to September 22). The PMN is now the subject of a section 5(e) consent order that is under negotiation. EPA told Company F that it will be weeks before the draft consent order arrives because EPA is backlogged drafting consent orders.

- Company G submitted a PMN in April 2016. EPA dropped the PMN from further review in April. Like other PMNs pending on the date of enactment, the review period was reset on June 22. In late July, EPA contacted Company G to inform it that the PMN had been scheduled for a Focus Group Meeting in early August. After the Focus Group Meeting, the program manager informed Company G that the PMN substance was assessed as not likely to present an unreasonable risk. In September, Company G received a call inquiring about downstream customers and the potential for inhalable dust. Later in September, Company G received an "URGENT NEED TO COMMUNICATE" message. Company G was informed that the PMN went to another final Focus Group Meeting and the "not likely to present an unreasonable risk" determination had been revised to an

"insufficient information" determination and that the PMN substance will be subject to a section 5(e) consent order, and that Company G must await the consent order letter to be informed of the terms. Company G is still awaiting receipt of that letter.

Testing Requirements That Are Not Justified

- Company H submitted a PMN prior to enactment of the LCSA. EPA dropped it from further review prior to enactment. After enactment, EPA notified Company H that its PMN review period had been reset as of June 22. EPA is now requiring an up-front test that is not scientifically justified under the circumstances. The substance is water soluble in a roller application – its intended use. EPA is demanding the testing based on the fact that EPA cannot assess the inhalation potential from the roller. Company H does not understand why EPA is concerned about inhalation because the chemical is not being sprayed. The substance is not a VOC, and there is no analytical method to measure and provide EPA with the data it seeks. Company H is moving to contingency plans until it decides how to proceed in this new climate that is thwarting innovation.

- Company I has a vendor that submitted an LVE for a material that Company H wants to use (with the goal of protecting CBI), so Company H filed a proprietary use document with EPA as a supporting document to the vendor's LVE. Company I received three calls from EPA's engineer to have Company I explain what a "10% weight solids in a pre-mixture tank" contained in the PMN means in reference to a particular application that no one had identified as an intended application.

- Company J has been notified verbally that EPA intends to issue an "insufficient information" finding for a PMN on an intermediate. Prior to enactment of the LCSA, Company I discussed with EPA reviewers some potential ecotoxicity concerns that were resolved and the PMN was going to be dropped. EPA recently informed Company J that on re-review of the PMN, it had identified potential reproductive/developmental toxicity risks. EPA will issue a section 5(e) consent order requiring a reproductive and developmental study prior to manufacturing. In addition, EPA expects to add triggered ecotoxicity testing to the consent order and that the conditions of the consent order are subject to change as it goes through the approval process. Company J finds EPA's initial conclusions unexpected and unreasonable, for the following reasons:

    - The reproductive and developmental hazards had not been raised during previous risk assessment discussions; only the ecotoxicity concerns had been raised. Company J understood that those concerns had been adequately addressed.
    - The intended use of this substance is as an intermediate at Company J's manufacturing plants, where exposure and environmental releases are controlled. EPA does not appear to be considering exposure controls (or a non-section 5(e) SNUR to control uses) to mitigate potential risks in place of testing.
    - The proposed testing requirements are onerous – including lengthy and expensive studies prior to commencement of non-exempt manufacture.

- Multiple companies are reporting that EPA is frequently requiring 90-day inhalation studies on PMN substances without any use-based justification, i.e., the product as used is does not have potential inhalation exposure.

PPE No Longer Considered When Evaluating PMNs

- Program managers have reported to ACC members that PPE can no longer be considered to mitigate exposure and lower risk when there is potential for human health hazards. The risk has to be determined assuming there is no PPE. Because of data gaps, especially for chronic endpoints, this is often yielding the determination that EPA has "insufficient information" to assess risk and it will require up-front testing. Program managers have stated that this will impact significantly higher molecular weight polymers, as frequently EPA lacks information on them.

- Company K reported that EPA was about to issue a non-section 5(e) SNUR with a release to water trigger the day after enactment of the LCSA. EPA then re-evaluated the PMN and revised its finding to find an ecotoxicity concern and make an "insufficient information" determination regarding mutagenicity. The program manager mentioned that, in the past, EPA would require PPE to mitigate the risk since the concentration was low and exposure was low, but that the Agency has now changed its approach. Rather than issue a SNUR and moving on, up-front mutagenicity testing will be required. This chemical is very low volume and is used in UV curable inks, coatings, adhesives at a maximum concentration of ~5%.

Strict Requirements on Polymers and Consent Orders on Polymers Meeting the Polymer Exemption Criteria

- Company L submitted a PMN for an acrylate polymer. EPA called to request a suspension of the review period so that it can prepare an "insufficient information" section 5(e) consent order that would prohibit releases to water. EPA would consider removing that requirement if Company L completes testing, which has yet to be determined. While the average molecular weight of the polymer is at the low end of the Polymer Exemption criteria, it is surprising that EPA is interested in regulating it when it likely meets the low-risk criteria of the Polymer Exemption.

- Company M's PMN on a polymer had its review period reset on June 22. EPA then requested a suspension to complete a section 5(e) consent order. Company M requested the Action Letter and was told it cannot be provided until finalized and signed. Company M requested the engineering report, but it has not yet been received. The program manager has informed Company M that the consent order will be very different from anything it has seen in prior SNURs for this chemistry.

- Company N has 16 PMNs (a number of which are polymers) and 2 LVEs in review. Of these, one PMN has received a "not likely to present an unreasonable risk" determination. The review periods for the other 15 PMNs and the 2 LVEs have been suspended. Seven of these have pending section 5(e) consent orders. The outcomes of the remaining 10 are

currently not known. Two of the PMNs had been submitted prior to enactment and had been dropped prior to enactment, but are now subject to consent orders.

- Company O expects a section 5(e) consent order on a polymer that meets the polymer exemption criteria. Company O does not understand the explanation provided by EPA as to what it is about the polymer that EPA is trying to control.

- Company P has several examples of EPA trying to control the molecular weight of prepolymers and polymers. While there may be some justification for this approach, manufacturers need practical flexibility. EPA should not force manufacturers to adhere to exact values because the molecular weight may be reported in the PMN from lab samples, but when a company scales up to a commercial run, the molecular weight can change slightly.

- Company Q filed a PMN in May on a polymer with a high molecular weight. The PMN was dropped from further review before enactment of the LCSA. After enactment, EPA reset the review period. This material is site-limited and completely consumed onsite. EPA informed Company Q that it was concerned about inhalation issues/lung overload and it wanted a 90-day inhalation test with a 60-day holding period (totaling 5 months). Company Q explained that the material would never be respirable, which was reflected in the shaking test in the PMN. EPA has nevertheless requested another 15-day review and asked Company Q to send in more written material, which it is providing.

Philosophical Change in Approach

- Multiple companies report a marked change in philosophy and approach at EPA. Whereas EPA used to work more collaboratively with PMN submitters to work through issues and concerns, since enactment of the LCSA, EPA is issuing unwarranted demands, and requiring unjustified section 5(e) consent orders without adequately consulting with PMN submitters. EPA is requiring information on potential conditions of use downstream, requiring up-front testing for those uses, and requiring companies to provide a compelling argument regarding its proposed use of the chemical to get approval. The consent orders are requiring companies to commit to only the use identified in the PMN and no releases to water.

Consistent Refusal to Issue Non-Section 5(e) SNURs

- Many companies report being told that EPA can no longer issue non-section 5(e) SNURs.

- EPA representatives told the U.S.-Canada Regulatory Cooperation Council (RCC) in September that non-section 5(e) SNURs "are not really a thing and never were . . . ." When pressed on this point, EPA said they would double check and clarify. EPA sent ACC an email citing the following Q&A from the FAQs and asked if this responded to the inquiry:

Q14. Does EPA still see a continuing role for non-section 5(e) significant new use rules (SNUR) under the new law?

A: The Agency's authority to issue SNURs derives from section 5(a)(2) – not section 5(e). Section 5(a)(2) was not changed under the recent amendments to TSCA. The Agency fully expects to continue to exercise its SNUR authority, as appropriate, in the context of both new and existing chemicals.

Unfortunately, this Q&A does not address this question.

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 4/16/2018 7:58:23 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Polymer issue
Attachments: 00238875.docx; Our Glove Discussion; TSCA NCC and Mandated OSHA Consultation for New Chemicals

Erik:

Good speaking with you. As promised, we append:

- Chronology of the "polymer" issue we discussed (unrelated to your inquiry, but pertinent to our "glove" issue)
- The glove information is the "Our Glove Discussion" attachment
- The "TSCA NCC " attachment reflects the thoughts we shared with Jeff and OSHA pertinent to EPA OPP/OSHA overlap concerns related to all of the above

Rich and I would be pleased to speak anytime if it helps resolve these resolvable issues.

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson
Sent: Friday, April 13, 2018 6:53 PM
To: Ryan Schmit
Cc: Richard E. Engler, Ph.D.
Subject: Polymer issue

Ryan,

A summary of this issue is attached.

Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

Polymer Issue Chronology
April 13, 2018

- In 2011, EPA was engaged in an OECD lead initiative, Clearing House on New Chemicals (CHNC), to expand the list of polyesters qualifying as "polymers of low concern."
- CHNC included the EU, U.S., Canada, and Australia.
- The CHNC work group developed criteria to support a determination that a substance is "equivalent" to a reactant that is listed on the list of "approved polyester reactants."
- The work group agreed that phthalic anhydride and phthalic acid are "equivalent" because the polymers formed are indistinguishable and, accordingly, a polymer produced from phthalic anhydride could be eligible for the polymer exemption.
- Canada and Australia have already implemented this change in their respective regulatory programs.
- The EU reportedly did not adopt the change, largely for political, not scientific, reasons.
- Based on a call we had with Greg Schweer last fall, we understand EPA's efforts to implement the change were delayed when resources shifted to TSCA implementation.
- Our client manufactures polymers and routinely relies on the polymer exemption.
- To qualify for the polymer exemption as a polyester, the polymer must be manufactured solely from a list of acceptable reactants.
- One reactant our client uses is phthalic anhydride, which is not listed in the list of acceptable reactants codified at 40 C.F.R. Section 723.250(e)(3) ((e)(3) exemption).
- A closely related substance, phthalic acid (1,2-benzenedicarboxylic acid, CAS RN 88-99-3), is listed.
- As noted, polymers manufactured from either phthalic acid or phthalic anhydride are indistinguishable. During the polymerization reaction, reaction between phthalic anhydride and one or more di- or polyfunctional alcohol produces the same polymer as is formed by the reaction between phthalic acid and the same alcohol(s). No anhydride functionality remains.
- Our client submitted a consolidated set of two PMNs (P-17-0306 and P-17-0307). Both are polyesters based on phthalic anhydride. One of the two (P-17-0307) is a polymer of soybean oil, diethylene glycol, terephthalic acid, and phthalic anhydride. If the phthalic anhydride were in the form of phthalic acid, this polymer would be eligible for the (e)(3) polyester polymer exemption.
- In its review of P-17-0306 and 0307, EPA identified a potential hazard to workers from low molecular weight polyesters and found that impervious gloves would protect workers from any potential exposure. EPA proposed a non-order SNUR obligating workers reasonably expected to be exposed to wear impervious gloves.
- Our client argued that these polyesters are only used in an industrial setting as intermediates to other polymers, and impervious gloves are routinely worn by workers. As such, our client argued that it is not reasonably foreseeable that workers would be

dermally exposed to low molecular weight polymers. EPA asked that our client obtain glove data to prove workers wear gloves. To our knowledge, no such data, beyond what we submitted to EPA, exist. (*See* attached e-mail).

- We believe that OPPT can maximize its investment in another PMN submission (**P-17-0307**) and develop a review process for other polyesters in this class (*i.e.*, those manufactured using phthalic anhydride instead of phthalic acid, but are otherwise eligible for the (e)(3) exemption). We proposed a process similar to the one suggested below:
  - Using one of the current PMNs as a template, urge the *ad hoc* group to acknowledge that a polyester in this class is not likely to present unreasonable risk under the reasonably foreseeable conditions of use based on the fact that it is reasonably foreseeable that gloves will be used during manufacturing, processing, or use of such polyesters.
  - Direct the new chemicals review team that polymers that meet the (e)(3) criteria but for the use of phthalic anhydride as a monomer will be sent on a short-cut to a not likely determination (parallel to old CRSS drops). This would essentially create a quasi-exemption -- notification is required, but substances that meet this class of polymers are "not likely."
  - In this way, EPA clears a path for polymers that will be exempt when the (e)(3) criteria are updated to proceed to commercialization. This also avoids a group of polyesters that were drops under old TSCA, are currently being regulated with SNURs, and will be exempt.
  - Manufacturers who ended up with regulated polyesters during the window between June 22, 2016, and the point at which the polymer exemption rulemaking is complete (several years from now) will have products that are uniquely disadvantaged simply because of the timing of their commercialization.
- We have met with OPPT twice on the issue, last December and earlier this year, and, as Jeff knows well, have had several calls on the issue.

Hope this helps.

Attachment

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 3/28/2018 11:50:33 PM
To: Morris, Jeff [Morris.Jeff@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Our Glove Discussion

Hello Jeff:

This supplements our discussion during our meeting on February 21, 2018, during which you challenged us to find support for the proposition that gloves are routinely used in the workplace in connection with protecting workers who might otherwise be exposed to industrial chemicals. You asked us to find support for this view in response to our view that it is not a reasonably foreseen condition of use that workers would not be wearing gloves in workplace settings that include industrial chemicals.

We first conducted a literature search to identify any articles or surveys that might be useful. We found none.

Next, we reviewed OSHA, NIOSH, and ACGIH websites to see if any of these organizations reported on industrial glove use and/or other data that may be useful. We found none.

Next, I spoke with both the President and the Director of Government Affairs (two separate people) of the American Industrial Hygiene Association (AIHA) to see if AIHA kept records of any sort that may be responsive to your request. AIHA reports that they do not maintain any data that would be pertinent or helpful.

Since I am on the Board of Directors of the Product Stewardship Society and its President-Elect, https://www.productstewards.org/Pages/default.aspx, I sent an e-mail to my fellow Board members. None was aware of any such information, but suggested I speak with several "Deans" of the industrial hygiene industry. Specifically, we spoke with:

- John R. Mulhausen, Ph.D. CIH -- retired 3M (former head of industrial hygiene) -- was unaware of any such information.

- Robert (Bob) Phalen, Ph.D., CIH -- University of Houston, Clear Lake (current chair of the AIHA Protective Clothing and Equipment Committee) -- was aware of no such information and expressed surprise that gloves would be a requirement under TSCA because the hazard evaluation required under OSHA would result in appropriate glove selection.

- Zack Mansdorf , Ph.D., CIH, CPS, QEP -- past President, AIHA -- was unaware of any such information and expressed his view that gloves would be worn based on MSDS OSHA requirements.

We also reached out to several U.S. glove manufacturers (Ansell Protective Solutions, Northern Safety Co., Inc., and Lakeland Industries, among others). All reported that data along the lines EPA seeks were not maintained by these organizations largely because the type of glove manufactured and offered for sale was dependent entirely upon the chemical at issue and the type of glove best suited to address exposure to it.

We also found helpful OSHA's own enforcement statistics, which find that non-compliance with the OSHA glove standard is not among the top ten standards for which citations are issued:

The Top 10 for FY 2017* are:

1. Fall Protection; General Requirements (1926.501) – **6,072**
2. Hazard Communication (1910.1200) – **4,176**
3. Scaffolding (1926.451) – **3,288**
4. Respiratory Protection (1910.134) – **3,097**
5. Lockout/Tagout (1910.147) – **2,877**
6. Ladders (1926.1053) – **2,241**
7. Powered Industrial Trucks (1910.178) – **2,162**
8. Machine Guarding (1910.212) – **1,933**

9. Fall Protection – Training Requirements (1926.503) – **1,523**
10. Electrical – Wiring Methods (1910.305) – **1,405**

See http://www.safetyandhealthmagazine.com/articles/16217-fall-protection-leads-oshas-top-10-list-of-cited-violations.

In short, the data EPA seeks are not maintained by any organization, public or private, that we have identified. We suspect it is because glove usage is routine, common place, and an essential element of any private sector OSHA compliance program and/or sensible commitment to worker safety, not to mention a safeguard against private tort liability. Furthermore, the type of gloves that would be used are so specific to each workplace that evaluations on whether the correct gloves are used must be specific to the circumstances and would, therefore, not be amenable to a broad survey of glove use.

We would like to discuss next steps with you at your earliest convenience.

Lynn

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 12/14/2017 12:54:41 PM
To: Maureen Ruskin [ruskin.maureen@dol.gov]
CC: Kathleen M. Roberts [kroberts@bc-cm.com]
Subject: TSCA NCC and Mandated OSHA Consultation for New Chemicals
Attachments: 00225476.pdf; 00226510.pdf

Good Morning Maureen:

I hope you are well. I write this morning to share with you information pertinent to the U.S. Environmental Protection Agency's (EPA) implementation of amendments to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, related to EPA's revisions to TSCA Section 5 (new chemicals). We represent the TSCA New Chemicals Coalition (NCC), a coalition of over 20 company representatives, formed to work collaboratively with EPA on Section 5 implementation issues.

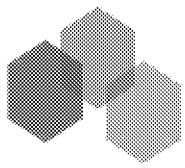
Appended is a letter to Dr. Jeffery Morris, EPA, regarding the mandated EPA consultation process with the U.S. Occupational Safety and Health Administration (OSHA) under TSCA Section 5(f)(5), (document number 226510). Also appended is a written analysis, TSCA New Chemicals Coalition Position Statement Concerning the Consultation with OSHA Required by New TSCA and EPA Adoption of Restrictions to Address Workplace Exposures, December 2017, which is referenced in the Morris letter (document number 225476).

We would welcome an opportunity to visit with you, and/or pertinent others on your team, to discuss these matters. We are also coordinating accordingly with the Small Business Administration.

Best wishes for a Happy Holiday season,

Lynn

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com



TSCA
NEW CHEMICALS
COALITION

TSCA New Chemicals Coalition[1] Position Statement Concerning the Consultation with OSHA Required by New TSCA and EPA Adoption of Restrictions to Address Workplace Exposures
December 2017

I. ISSUES TO BE RESOLVED

The TSCA that was originally enacted in 1976 was comprehensively restructured and revised in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (new TSCA). New TSCA generally requires EPA to issue an order under Section 5(e) governing the manufacture, processing, distribution, use, or disposal of a new chemical substance whenever EPA makes a determination under Section 5(a)(3)(B). EPA is directed to "prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance … to the extent necessary to protect against an unreasonable risk of injury to health or the environment." As part of this determination, EPA must consider risks "to a potentially exposed or susceptible subpopulation" that EPA deems relevant, which typically will include workers who are occupationally exposed to the new substance during the manufacture, processing, or use of the substance.

While EPA may issue an order under new TSCA Section 5(e) that contains prohibitions or restrictions intended to address workplace exposure, new TSCA Section 5(f)(5) requires that, prior to doing so, "[t]o the extent practicable, [EPA] shall consult with the Assistant Secretary of Labor for Occupational Safety and Health…." This required consultation with the U.S. Occupational Safety and Health Administration (OSHA) is vital as it both acknowledges a role for EPA concerning workplace exposures and explicitly recognizes OSHA's primary responsibility for protecting worker safety and health. TSCA NCC believes that the clear intent of the consultation provision is to require that EPA, before deciding to implement separate TSCA action, will jointly evaluate the contemplated regulatory approach with OSHA, thereby assuring that EPA adequately considers OSHA's established regulatory programs and avoids conflicts or confusion in addressing and mitigating worker exposure risks to a new chemical substance. Section 5(f)(5) addresses the need for consultations "prior to adopting *any* prohibition or other restriction" (emphasis added). Without such ongoing consultations, TSCA NCC believes that EPA's adoption of restrictions for a new chemical to

---

[1] The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the new TSCA and to work collaboratively with the U.S. Environmental Protection Agency (EPA) to address these issues.

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: 202-557-3801 | F: 202-557-3836

address workplace exposures that are also regulated by OSHA would inevitably increase the potential for conflicts concerning -- or material differences in interpretation -- of these parallel requirements.

The value of coordination was recognized in a 1981 Memorandum of Understanding (MOU) between EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS), a predecessor of the current EPA Office of Chemical Safety and Pollution Prevention (OSCPP) (attached). The MOU included provisions relating to sharing of information and joint participation in reviews and regulatory determinations on new chemicals presenting an occupational concern as well as sharing of confidential business information (CBI).

Section 4(b)(1) of the Occupational Safety and Health (OSH) Act, which addresses preemption of OSHA's regulatory authority in certain instances, states: "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies … exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." An MOU entered into by EPA and OSHA on February 13, 1991, affirms that OSHA retains principal "broad authority" to regulate workplace exposures to chemicals, while "EPA responsibilities include the protection of public health and the environment." The comprehensive OSHA Field Operations Manual (FOM) (2016), in explicitly addressing the effect of this preemption provision, observes that the only group of workers for whom OSHA regulation is considered to be preempted by EPA authority are farmworkers and pesticide applicators directly exposed to pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), for which the worker protection measures in the EPA-approved label instructions preempt OSHA. While changes in the regulatory landscape may change the scope of preemption as well, as the FOM notes, how it is delineated can be a complex determination. It would be inappropriate for EPA to presume that it has been afforded broad authority under TSCA Section 5(e) to make independent regulatory decisions affecting areas that have been in OSHA's domain for decades.

TSCA NCC's reading of the effect of Section 5(f)(5) does not suggest that Congress, in amending TSCA, intended to supplant OSHA's regulatory authority over workers exposed to any chemical substance that is "new" for TSCA purposes. For this reason, it would be prudent to minimize the likelihood that EPA's regulatory activities affecting occupational exposures to new chemicals may be construed to preempt OSHA's authority to regulate exposures of those same workers. TSCA NCC believes that a robust consultation process that assures that EPA does not unnecessarily encroach on OSHA regulation should suffice to prevent any unintended preemption. Furthermore, TSCA NCC believes that the existing 1991 MOU

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: 202-557-3801 | F: 202-557-3836